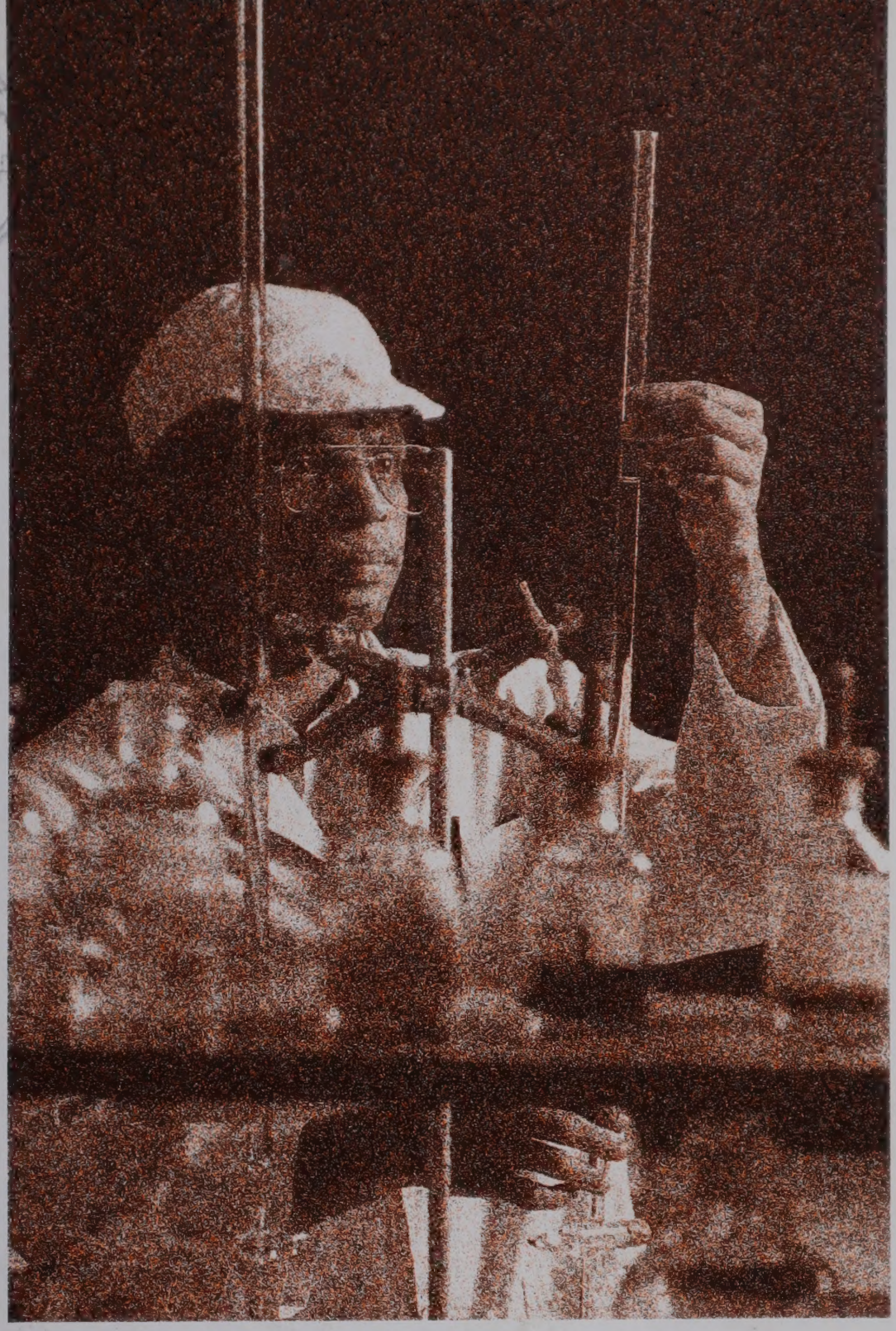
COMMUNITY HEALTH
LIBRARY
AND
DOCUMENTATION
UNIT
BANGALORE.

IOCU



FROM POLICY *TO* *practice*

The future of the Bangladesh National Drug Policy

Andrew Chetley

02559

From Policy to Practice

COMMUNITY HEALTH CELL
Library and Information Centre
No. 367, Srinivasa Nilaya, Jakkasandra,
I Main, I Block, Koramangala, Bangalore - 560 034.

THIS BOOK MUST BE RETURNED BY
THE DATE LAST STAMPED

From Policy to Practice

The Future of the Bangladesh National Drug Policy

BY

Andrew Chetley

INTERNATIONAL ORGANIZATION OF CONSUMERS UNIONS
Penang • Malaysia

About IOCU

The International Organization of Consumers Unions (IOCU) is a federation of consumer organisations dedicated to the protection and promotion of consumer interests worldwide through research, information and education. An independent, non-profit foundation registered in the Netherlands in 1960, IOCU currently links the acitivities of some 180 consumer groups in about 70 countries and represents the consumer interest at international fora. IOCU operates from its regional offices in Penang, Malaysia for Asia and the Pacific; The Hague, the Netherlands for Europe and North America and Santiago, Chile for Latin America and the Caribbean, and its Director-General's Office in London, UK.

About the Author

Andrew Chetley is a Canadian-born research and development consultant, journalist and campaigner. For 11 years he worked for the British development NGO, War on Want, and for nearly four years, he worked for the Dutch-based Bernard van Leer Foundation, which concentrates on support for programmes to encourage early childhood development and education. He has worked for and advised several international networks of NGOs on health, development and environmental issues, including the International Organization of Consumers Unions (IOCU), the International Baby Food Action Network (IBFAN), Health Action International (HAI) and the Pesticides Action Network (PAN). He has contributed articles to numerous publications, including *The Lancet*, *World Health*, *Development Dialogue*, *Development Forum*, and the Gemini News Service. He is also the author of a number of reports. His books include:

The Baby Killer Scandal, 1979, London: War on Want
The Politics of Baby Foods, 1986, London: Frances Pinter
Antibiotics: the wrong drugs for diarrhoea, 1987, The Hague: Health Action International (HAI)
Peddling Placebos: an analysis of cough and cold remedies, 1989, Amsterdam: HAI
A Healthy Business?, 1990, London: Zed Books
The Power to Change, 1990, The Hague: Bernard van Leer Foundation
Promoting Health or Pushing Drugs?, 1992, with B. Mintzes, Amsterdam: HAI

ISBN: 967-9973-65-4
Copyright © IOCU 1992

DR415
N92

02559

Produced by
International Organization of Consumers Unions
Regional Office for Asia and the Pacific
PO Box 1045, 10830 Penang, Malaysia.

design: Susan Siew
cover photo: Shehzad Noorani/UNICEF
charts and graphs: Andrew Chetley
production: Lin Min Min
printing: Jutaprint Penang Malaysia

Contents

TABLES

FIGURES

BOXES

Acronyms & abbreviations

ACI	Advanced Chemical Industries (Bangladeshi company)
ADR	adverse drug reactions
AHI	assistant health inspector
BASS	Bangladesh Aushad Shilpa Samity (Bangladesh pharmaceutical industry association)
BBS	Bangladesh Bureau of Statistics
BMA	Bangladesh Medical Association
BPC	Bangladesh Pharmacy Council
BPS	Bangladesh Pharmaceutical Society
BRAC	Bangladesh Rural Advancement Committee
DANIDA	Danish International Development Agency
DCC	Drug Control Committee
DDS	drug and dietary supplement (kits, of UNICEF)
DTL	Drug Testing Laboratory
EDCL	Essential Drugs Company Limited (Bangladeshi company)
FDA	Food and Drug Administration (US)
FICCI	Foreign Investors Chamber of Commerce and Industry
FPA	family planning assistant
FWA	family welfare assistant
FWV	family welfare visitor
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
GNP	Gross National Product
GOB	Government of Bangladesh
HA	health assistant
HFA	Health for All
IFPMA	International Federation of Pharmaceutical Manufacturers Associations
IOCU	International Organization of Consumers Unions

IPGMR	Institute of Post Graduate Medicine and Research
IUD	intrauterine device (contraceptive)
LDC	least developed country
MOH&FW	Ministry of Health and Family Welfare
MRP	Maximum Retail Price (of drugs)
NDP	National Drug Policy
NGO	non-governmental organisation
NIPSOM	National Institute of Preventive and Social Medicine
ODA	Overseas Development Administration (UK)
ORS	oral rehydration salts/solution
ORT	oral rehydration therapy
OTC	over the counter (drugs)
OTEP	oral therapy extension programme (of BRAC)
PHC	primary health care
PMA	Pharmaceutical Manufactuers Association (US)
PPU	Pharmaceutical Production Unit
SIDA	Swedish International Development Authority
SKF	SmithKline and French (multinational company)
UBINIG	Policy Research for Development Alternative (Bangladeshi NGO)
UHC	upazila/thana health complex
UHFWC	Union Health and Family Welfare Centre
UNDP	United Nations Development Programme
UNICEF	United Nations Children's Fund
WHO	World Health Organization

COMMUNITY HEA
LIBRARY
AND
DOCUMENTATION
UNIT
BANGALORE.

Acknowledgements

This report would not have been possible without the cooperation of more than 50 people who I talked with during the five weeks I spent in Bangladesh in mid-1992. They include government officials, representatives from national and multinational pharmaceutical companies, academics and researchers, practicing physicians and health workers, pharmacists and retail dispensers, representatives from international organizations working in Bangladesh, from several donor agencies and from some of the local and international non-governmental organzations active in the country in the field of health and some media representatives. Some of these people asked to remain anonymous and, in exchange for frank discussions and some clear insights into the issues related to the Bangladesh National Drug Policy, I have respected that wish and also extended it to include most of the people I talked with. Exceptions are those people who are public figures and who have been quoted recently in the media in Bangladesh saying something similar to what they told me. In those cases, I felt that many of their views on the subject were already a matter of public record and therefore a report of our conversation would not compromise their position.

I also have to thank the staff of both UNICEF and Oxfam in Dhaka who helped to facilitate my stay, provided me ideas of people to meet with and access to background documentation, and made the logistics of the visit effortless, at least to me. Similarly, the staff at the IOCU Regional Office for Asia and the Pacific in Penang, Malaysia deserve thanks for finding me space on their computers while I finalised the draft of this report, and for all the other support they provided. Staff of all three organizations also contributed valuable comments on the draft which helped to improve it considerably.

Special thanks go to Bazhul Huq, a former assistant director of the Drug Administration in Bangladesh, who worked with me for three weeks during my visit, helping to arrange meetings, collect information, and interpret the way in which the drug regulatory mechanisms operate. His assistance was invaluable and has helped to make this report more substantial.

Dr Humayun K.M.A. Hye, former director of the Drug Administration, also deserves mention. His considerable work in collecting a wide range of data about the production and supply of drugs in Bangladesh and his insights into the issues were of much help. So too was an informal report that he prepared on the topic which was both a useful source and an indicative guide for the preparation of this report.

The contributions of all the people who have had an opportunity to influence this report have added to its depth and to its value. They can be praised for the positive aspects of the report. Ultimately, however, I take responsibility for the final text: it is a personal appraisal of the National Drug Policy of Bangladesh and an assessement of possibilities for the future.

It is as comprehensive as possible, but any errors of commission or omission are mine. Like the Policy itself, this report is not the definitive answer to improving the supply and rational use of drugs. It is merely a contribution to the process of discussion that must go on if medicines are to find their true place in the health care system of Bangladesh.

ANDREW CHETLEY
The Hague
September 1992

Foreword

Drugs are an important part of health care, both to prevent as well as to treat illnesses. The consumers' demands of drugs are straight forward: that they be effective, reasonably safe, available and affordable. In many Third World countries we see the paradox of the shortage of essential drugs for the most common diseases existing side by side an over production of non-essential and, even spurious, drugs. A new paradigm is needed to ensure that the consumers' basic demands are met.

One Third World country made this radical move. In 1982 the Government of Bangladesh passed the New Drug Policy (Ordinance) consisting of various measures to reduce drug prices, to encourage higher domestic production of essential drugs and to focus the use of drugs to meet the couuntry's health needs.

The Policy was not met with unanimous support. There was fierce opposition from within and without and there were problems in its implementation. There had been times in the the last ten years when there was real danger that the policy might have been abandoned or weakened.

From the beginning IOCU had felt that the Bangladesh Drug Policy was worthy of support. If it succeeded, consumers in Bangladesh would benefit. So in 1986, four years after the introduction of the policy, IOCU commissioned a progress report (*Essential Drugs: the Bangladesh Example – Four Years On* by Dexter Tiranti, IOCU, Penang, 1986). The findings were encouraging: already there were better quality, cheaper and more essential drugs. Bangladesh, however, still faced serious obstacles including an overstretched Drug Administration; inadequate quality control and lack of support from the medical profession.

Now ten years on, we wondered if the earlier gains have been maintained and the difficulties overcome. This report *From Policy to Practice: the future of the Bangladesh National Drug Policy* by Andrew Chetley evaluates the situation. It was a pleasure working with Andrew Chetley whose sharp research skills and tremendous hard work produced this report in a remarkably short time. We are also grateful to UNICEF and OXFAM in Dhaka for not only funding this study but also for their assistance throughout the project.

The experience of Bangladesh in shaping the production and use of drugs to meet the health needs of its consumers is a worthy example to other countries who share the same goal.

FOO GAIK SIM
Director
IOCU Regional Office for Asia and the Pacific
Penang, Malaysia

Summary

BANGLADESH WAS THE FIRST country to develop a policy based on internationally accepted public health concepts such as primary health care and the need for essential drugs. In June 1982, Bangladesh introduced a National Drug Policy (NDP) and a Drugs (Control) Ordinance. The main objectives of the NDP were to:

- increase availability and accessibility of good quality essential drugs;
- eliminate useless, non-essential and potentially hazardous drugs from the market (this was taken to include allopathic, homeopathic, and traditional Ayurvedic and Unani medicines);
- encourage local manufacture of drugs and raw materials, particularly essential drugs; and
- develop appropriate legislative and administrative mechanisms.

The Drugs (Control) Ordinance provided the legislative framework for the NDP and also allowed the government to fix maximum prices for the import or sale of raw materials and for the retail sale of finished drugs.

The NDP led to the selection of 250 essential drugs (now 302) and to the banning of 1,666 products that were useless, ineffective or harmful.

The success of the Drug Policy

Over the past decade, the Drug Policy has gone some way towards meeting many of its objectives. These achievements include:

- increased local production of essential drugs;
- stable drug prices;

- a greater share of production by national companies;
- less dependence on imported products and increased savings;
- less waste of resources on non-essential or useless products; and
- an improvement in the quality of drugs.

More essential drugs

The value of local production of drugs has increased by more than 217% in local currency terms. The production of essential drugs has also increased from 30% of local production in 1981 to 80% in 1991. This has been described as 'the number one achievement of the drug policy.'

Stable drug prices

Raw material prices have been dramatically reduced. Retail prices, too, have been held down. Between 1981 and 1991-2, the retail price of 25 major drugs has increased an average of 20% in local currency, but has declined by more than 40% when the prices are converted to US dollars to take into account inflationary effects. Compared to the consumer price index, which rose by 173% (in local currency) during the same period, in real terms, drugs have become more accessible and affordable to people in Bangladesh.

Bangladeshi companies gain a bigger share

In 1981, eight multinational companies controlled 65% of the local production and about 75-80% of total sales, including about 80% of sales to the government sector. By 1991, Bangladeshi companies controlled more than 60% of the local production, with one national company supplying about 70% of the government sector's drugs requirements.

Decreased dependency and increased savings

Prior to the NDP, half the drugs considered essential for public health were not being manufactured in Bangladesh. In 1981 one-third of the import bill was for finished drugs, but in 1991, it was less than one-eighth.

The import statistics, however, do not show what might have happened if there had been no Drug Policy. If the dependence on imported drugs had continued over the past 10 years, an additional US$186 million would have been required to pay for the imports of finished drugs.

As well, in 1981 about one-third of all production went on useless products. If there had been no Drug Policy and this unnecessary production had continued, more than US$436 million would have been wasted. In total, then, the NDP has saved the country and its people more than US$620 million.

Better quality

Drug samples tested over the years by the national Drug Testing Laboratory (DTL) show an improvement in quality. In 1981, 36% of samples tested were substandard compared to only 9% in 1991. There is, of course, still considerable room for improvement.

The policy today

Despite these successes, the NDP has come in for criticism over the years. Much of the criticism has come from the industry and from the medical establishment in the country, both of which feel that they were not adequately consulted about the NDP. The government has now appointed a committee to review the NDP whose composition reflects many of the key actors in the drugs debate. Achieving a balance between the commercial and health needs is the major challenge, not just for the review committee, but over the next 10 years and beyond, for the people of Bangladesh.

Among the arguments the review committee will be facing are claims that the NDP has:

- driven away foreign investment;
- encouraged smuggling of banned drugs;
- led to people not having access to the latest life-saving drugs;
- hampered the growth and development of the pharmaceutical industry by excessive regulation and unworkable price controls;
- unfairly restricted the production choices of multinational companies; and
- failed to deal with poor quality products.

Flight of foreign investment?

The claim that the NDP is driving away foreign investment lacks any evidence. Pharmaceutical companies that have disinvested in Bangladesh have done so because of the dynamics of the wider global market and the effects of the international recession.

Increased drug smuggling?

The smuggling of banned drugs is not a flaw in the Drug Policy. The solution rests in better enforcement by customs officials and the police, stiffer penalties for those caught and better education about which drugs are worth using. Many of the drugs being smuggled are those with a potential for abuse rather than essential medicines that are needed to improve health.

No access to life-saving drugs?

The Drugs (Control) Ordinance allows for the registration of products on the basis of their 'safety, efficacy and usefulness'. Some physicians and company executives argue that this deprives patients of the latest life-saving innovative products that are being sold in other countries. However, any drug can be registered provided those criteria are met. In exceptional cases, special dispensation can be granted urgently for the importation of a new product for a named patient.

Too many restrictions?

Another argument is that limitations on products should only apply to the government health sector and that the private sector should be free of any controls on the drugs that can be sold. With the public sector covering, at most, 40% of the country's health and medicine needs, such a position is unworkable. Policies applied only to the public sector rationalise but a smaller proportion of the drugs market.

Another approach to the private sector question comes from the industry argument that some 'home remedies' should be allowed to 'relieve symptoms and provide comforts to people'. Many of the products the industry hopes to get onto the market in this way are the 'unnecessary and useless medicines' that wasted people's money before the NDP. This goes against both the spirit and the letter of the NDP and is not in the best interests of public health.

Excessive price control?

The industry argues that price control is excessive and should be scrapped. However, most company officials do accept that the control on the price of imported raw materials has been beneficial and is acceptable. Most of the debate focuses on the retail price which, it is claimed, does not allow sufficient margins for future investment nor does it provide an incentive or reward for quality. Some flexibility in the price controls may be necessary.

A fair deal for multinationals?

The NDP prevents multinational companies from manufacturing antacids and vitamins, does not allow licensing agreements if the same or similar product is available or manufactured in the country, and prevents companies that do not have a factory in the country leasing spare capacity in another company's factory to manufacture drugs. These are seen by the multinational companies as a restraint to fair trade. However, there is international consensus that least developed countries like Bangladesh need criteria such as these to help develop their technological, commercial and economic base.

The solution to these issues may lie in allowing more flexible arrangements, subject to guarantees of inputs to improve the training of staff in local factories, to upgrade quality control practices, and perhaps to assist in the installation of new equipment. Licensing and other agreements should not lead to monopoly situations or prevent local production.

No quality control?

Most studies carried out on quality control in Bangladesh indicate that the companies at the bottom end of the market have the most problems with quality. The issue here is not so much with the NDP, which is clear about the need for high quality drugs, but with the inspection and enforcement mechanisms that need to be strengthened.

Towards the future

In all the criticism of the NDP, there is no real substantive point that makes it obvious why the policy should be scrapped. The problems lie more with the lack of effective implementation mechanisms than with the NDP itself.

The policy issues regarding pharmaceuticals have been largely decided upon within Bangladesh over the past 10 years. The supply of medicines and assuring their quality is being worked on – too slowly for some, perhaps. But the principal question that still remains, the one that probably has the most bearing on health, relates to the rational use of medicines.

Among the factors that have a major influence on the rational use of medicines are:

- the traditional system of healing;
- the dispensers; and
- the quality of education about health and drugs.

Traditional medicine

The vast majority of people in rural areas seek treatment from unqualified allopaths or traditional healers. Traditional healers are powerful potential allies in efforts to improve the rational use of drugs. By training them to diagnose and refer, and by helping them to realise the role of medicines – whether allopathic or traditional – in health care, they can become positive forces for change within communities, rather than obstacles to good therapy, which is how they are often viewed.

Quality control of traditional medicines has been described as varying from 'awful' to 'virtually non-existent'. Some success has been achieved in remov-

ing the most harmful of materials, such as heavy metals, from the medicines, but more could be done. The underlying philosophy of traditional medicine is herbs. By using only those herbs that are found to be safe and effective and by limiting combinations, a limited list of products could be developed.

Dispensers

In 1992, there were 20,000 licensed retail outlets for drugs. Unofficial estimates suggest that there are at least that number of unlicensed premises, plus an uncountable number of small shopkeepers and stallholders who have a few medicines along with their food products or cigarettes.

Most of the people running even the licensed shops are untrained. About 12,500 of them have had a short four-month training course that provided them with a certificate. A longer term strategy is needed to plan for the situation in the future. A starting point could be no new issue of licences unless basic ethical standards are complied with and unless adequate training has taken place. Existing licences for pharmacies should be ended when the present owners die. Existing dispensers need to have intensive and regular training courses. Incentives should be given to those who attend courses and put into practice the training.

Health education

Several recent studies have found that the knowledge of health workers is poor about the NDP, and the concepts of essential drugs and the rational use of drugs. Providing the general public and health workers at all levels of the health care system with continuous training and regular information are preconditions for rational drugs use.

There are conflicting views in Bangladesh about the quality of education that prescribers receive, especially with regard to the rational use of drugs. Although the medical curriculum now places more emphasis on community health care that is appropriate to Bangladesh, this still needs strengthening. Various courses and training programmes for doctors, nurses and grassroots level health workers have also been introduced by government departments and institutions as well as by NGOs. Most of these training programmes have emphasised motivation and commitment to primary health care.

Planning for the future

The problems that emerge in terms of the NDP, the rational use of drugs, and general improvements in the health care system are broadly similar. They include the absence of a formal national health policy, poor planning, the lack of an effective health manpower development strategy, little accountability,

weaknesses in training and education of health workers, little public education on health and rational use of drugs, and inadequate community involvement. The solutions to these problems are not easy, particularly when the country faces similar issues in other sectors. However, programmes operated by the government and by non-governmental organisations in several areas of the country have demonstrated that it is possible to tackle these issues.

While these are difficult challenges, the alternative – to simply let the health care system and the use of drugs evolve in an ad hoc manner – is to court chaos and continued inequity. Bangladesh has been a pioneer in focusing attention on the essential drugs concept and on the need to develop a drug policy. It can continue this pioneering work by focusing now on the implementation of the policy, by putting the policy into practice more effectively.

Recommendations for action

To do this, several actions can be taken. Some are simple and straightforward, some require long-term commitment.

Efforts to improve the effective implementation of the NDP itself include:

- having a regular review (every one to two years) of the list of essential drugs to keep pace with pharmacological developments;
- ensuring that the committees that are part of the drug regulatory system have technically competent members, adequate servicing, and meet regularly;
- improving the facilities and capabilities of the drug testing laboratories with additional equipment, staff and training;
- upgrading the ability of the Drug Administration to process applications for drug registration and for increasing inspections of production facilities.

The concerns around price control and the various questions about licensing agreements deserve special consideration. Two representative, but small, working parties should be set up by the government to consult widely on these topics and to bring forward workable recommendations that balance the health and industrial concerns.

Special efforts should be made to improve quality control measures. A more systematic programme of drug testing is required. Companies that are unable to meet basic quality standards should have their licenses revoked. Serious consideration should be given to relaxing excise duties on quality control equipment for manufacturers. Strategies for improving the quality control of traditional medicines need to be developed.

Health workers at all levels need to have better education about the rational use of drugs, including putting this in the context of community needs. This will require even more efforts to improve the medical curriculum and to strengthen in-service training for doctors and other health workers. Standard therapeutic guidelines for treating common diseases need to be developed. Particular attention should be paid to improving the training and education of grassroots health workers, given their importance in the country's health care system. In order for such improvements to have a positive impact, there needs to be a system to monitor the results of training, to audit prescribing practices and information transfer to patients and feed that information back into the system.

The public also needs education about when medicines are needed, which are effective, and how to take them. Consumer organisations and other NGOs can play a role in this. Training dispensers is another important area. Working with traditional healers, building on the strengths of existing community networks, will also encourage appropriate practices.

Benefits for everyone

It is understandable that business has found the NDP 'hostile', at times offensive, and certainly tough to live with. There will always be an uneasy tension between the health and business interests and the health concerns will have to remain the most important for some time to come. But business too can benefit from a focus on better health. Business has benefitted from the NDP, as have health workers and the people.

By revitalising its medical and pharmacy education and training, by improving education for consumers, by working more closely with communities to develop a health care system that meets the needs of the people, and by strengthening the regulatory and quality control mechanisms, Bangladesh can ensure that its people have access to the right drugs at the right price – and that they are used wisely.

Introduction

AT A CLINIC in Dhaka, Bangladesh, the first patient of the morning was a young boy of six. After a few questions to the boy's mother, and a simple examination, the doctor made the diagnosis – a parasitic infection – and prescribed the right medicine, something known to be effective against worms. As the child and his mother left the clinic, the doctor explained that the drug was effective and that the boy would soon be cured. He leaned back in his chair and sighed deeply. 'But within six months, he'll be back with another worm. And I'll prescribe another tablet, and so it goes on. You see, the child goes back into the same unsanitary environment and becomes re-infected.'

The doctor's next patient was a young baby girl. The baby was in good health and growing well, but it was time for a measles vaccination.

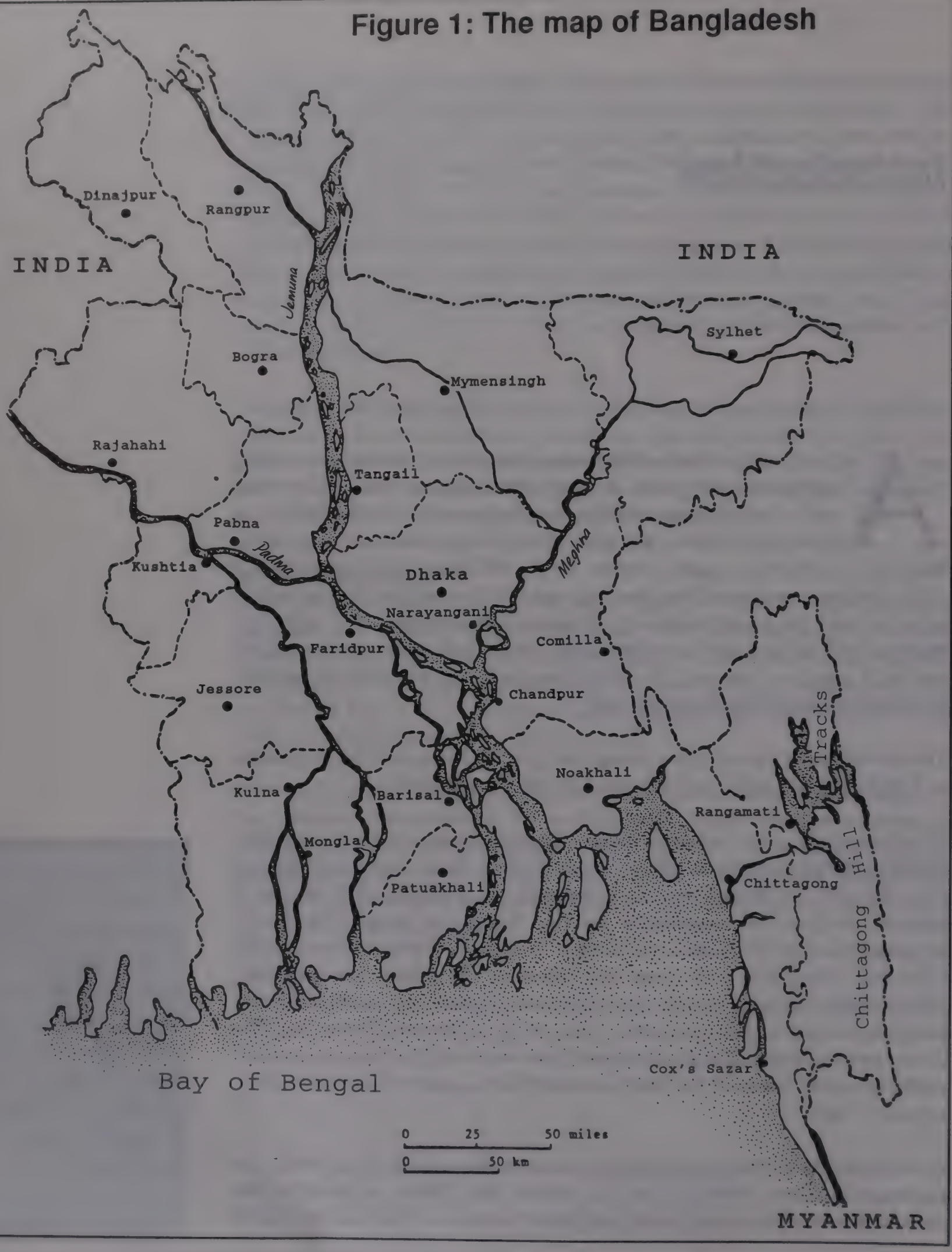
The third visitor was a salesman from a drug company, offering three new antibiotic treatments for diarrhoea in infants. The doctor listened politely to the sales talk as the representative brought out a dossier with copies of research studies that supposedly justified the use of drugs. The doctor skimmed through the studies and handed them back. 'These are seven, eight years old. Don't you have more recent studies?' he asked. The salesman, whose patter had been perfect up to that point, faltered. He muttered something about more recent experience, but nothing had been published yet. The doctor pointed out to the salesman that there were very few occasions when antibiotics were required for diarrhoea in children, and sent him on his way without a sale.

As he put away the free prescription pads advertising the products which the salesman had been trying to sell, the doctor said, 'What we need in this country are simple treatments and basic health education. Our doctors should

National drug policies and essential drugs programmes are now, and in the foreseeable future, the best means we have available of pursuing and eventually attaining the dual objectives of rational management of drug resources and better health for all.

– World Health Organization, April 1992

Figure 1: The map of Bangladesh



1. About Bangladesh

Bangladesh has a population of nearly 120 million people living in an area of some 144,000 sq. km. The country is divided into four administrative Divisions, 64 Districts, 460 Sub-districts (formerly called upazilas, but now called thanas), and 4,401 Unions. One of the world's least developed countries, Bangladesh faces the basic problems of poverty, unemployment, malnutrition, and high levels of illness, mortality and population growth.[1] According to nutritionist Alan Berg, 'the quality of human existence is the ultimate measure of development'.[2] The prevalence of sickness or morbidity in a population is one indicator of the quality of existence. In rural Bangladesh, the pattern of morbidity reflects characteristics of underdevelopment.[3] The population is predominantly rural, with some 57% of the labour force engaged in agriculture, another 34% in services, and less than 10% in industry.[4] External aid finances more than 90% of the annual development expenditure and foreign assistance accounts for about 10% of the country's gross domestic product (GDP).[5]

Basic data		Source
Population (1992)	117.2 million	Asiaweek
growth rate	2.7% per year	UNDP
below poverty line (%)	99.4 million (85%)	UNDP
urban (1990)	16%	UNDP
access to safe drinking water (1989)	60%	MOH&FW
access to sanitation (1985-88)	6%	UNDP
access to health services (1990)	45%	UNICEF
Crude birth rate	33/1000	BBS
Crude death rate	11/1000	BBS
Infant Mortality Rate (1990)	114/1000 live births	UNICEF
Maternal Mortality Rate (1989)	5.6/1000 live births	MOH&FW
Life expectancy (1991)	55.9 years	BBS
Per capita daily calorie intake (1989)	2,215 Kcal	BBS
Nutritional status of children (1990):*		
Normal	6.1%	BBS
Mild malnutrition	39.4%	BBS
Moderate malnutrition	47.2%	BBS
Severe malnutrition	7.3%	BBS
Per capita expenditure on health (1990)**	US$2.22	BBS
Per capita consumption of drugs (1990)	US$1.35	MOH&FW
Number of registered doctors (1992)	21,451	MOH&FW
Persons per doctor (1992)	5,473	
Number of registered nurses (1992)	9,274	MOH&FW
Per capita expenditure on education (1990)	US$3.77	BBS
Literacy rate (1991)	24.8%	BBS
Primary school enrolment rate (1986-88)	63%	UNDP
Primary school dropout rate (1986-88)	80%	UNDP
Gross National Product (per capita, 1989)	US$180	BBS
Average annual rate of inflation (1980-89)	11%	UNICEF

*nutritional status based on the Gomez classification
**includes expenditure on family planning

Sources: *Asiaweek* (7 August 1992). 'Vital signs', p. 7
BBS = Bangladesh Bureau of Statistics (1991). *Statistical Pocket Book of Bangladesh* 91. Dhaka: BBS
MOH&FW = Ministry of Health and Family Welfare (cited in various publications)
UNDP = United Nations Development Programme (1991). *Human Development Report 1991*. New York: Oxford University Press
UNICEF = United Nations Children's Fund (1991). *The State of the World's Children 1992*. Oxford: Oxford University Press

be able to deal with this. It is a tragedy that we can easily prevent many of the problems of infant health and don't do so.'

The telephone rang. It was a mother who had given birth the day before. She called to say that both she and the baby were fine and that she was breastfeeding and enjoying it. She thanked the doctor for all the help that he and the clinic staff had given in preparing her for breastfeeding. The doctor put down the phone and smiled. Another child was started successfully on the road to health.

The events in this doctor's clinic during less than 30 minutes encapsulate some of the major problems of health care in a developing country. In a dramatic way, they also highlight the benefits and failings of drugs. Some drugs, such as the anti-worm tablets, are effective but cannot get to the root causes of ill health: poverty, lack of sanitation and clean water, low levels of education and understanding about the causes of disease. Some drugs, such as the measles vaccine, are both effective and essential in helping prevent illness, even though in many countries, they are in short supply. Some drugs, such as antidiarrhoeal products containing an antibiotic, may be ineffective, certainly unnecessary and possibly harmful, yet these are often the most promoted products. And in many instances, the solution to health problems depends on non-drug therapies, such as the encouragement of and preparation for breastfeeding.[6]

Developing a drug policy

Those events took place in September 1982, barely three months after Bangladesh had introduced a strong National Drug Policy (NDP) and promulgated a Drugs (Control) Ordinance to provide the initial legal instrument for its implementation.

Described as a 'significant contribution' to the health care of the people[7] the NDP was an attempt to 'reduce the prodigious waste and misuse of modern therapeutic drugs' that occurs in most developing (and to a lesser extent, in industrialised) countries.[8] The main aim of the NDP was:

> to ensure that the common people get the essential and necessary drugs easily and at a cheap rate and to ensure that such drugs are good quality and are useful, effective and safe.[9]

The idea behind the NDP drew extensively on the concepts that were evolving internationally in the field of public health. In 1977, following the urging of the Non-Aligned Countries, the World Health Organization (WHO) issued a list of some 220 'essential drugs' as a guideline for governments.[10] WHO says

that the drugs on this list, which is regularly reviewed to keep pace with the development of useful new medicines, are adequate to meet more than 90% of the pharmaceutical requirements of developing countries.[11] This idea was firmly rooted in the efforts to encourage primary health care (PHC) that were further stimulated by the WHO/UNICEF co-sponsored International Conference on Primary Health Care held in 1978 at Alma-Ata in the then Soviet Union. The Alma-Ata Declaration has provided the guiding framework for many public health initiatives since that time (see Box 2 below).

2. Primary Health Care

Primary health care is essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination.

Primary health care includes:

- education concerning prevailing health problems and the methods of preventing and controlling them;
- promotion of food supply and proper nutrition;
- an adequate supply of safe water and basic sanitation;
- maternal and child health care, including family planning;
- immunization against the major infectious diseases;
- prevention and control of locally endemic diseases;
- appropriate treatment of common diseases and injuries; and
- provision of essential drugs.

It requires and promotes maximum community and individual self-reliance and participation in the planning, organisation, operation and control of primary health care, making fullest use of local, national and other available resources, and to this end develops through appropriate education the ability of communities to participate.

The people have the right and duty to participate individually and collectively in the planning and implementation of their health care.

Governments have a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measures.... All governments should formulate national policies, strategies and plans of action to launch and sustain primary health care as part of a comprehensive national health system.... To this end, it will be necessary to exercise political will, to mobilize the country's resources and to use available external resources wisely.

– From the *Declaration of Alma-Ata*, 12 September 1978

WHO has no doubts about the importance of a national drug policy:

> To ensure an adequate supply of safe and effective drugs of good quality at an affordable price, which are properly used, every country should have a national drug policy as an integral part of its health policy.[12]

Bangladesh was the first country to put the principles of Alma-Ata and of the essential drug concept into practice through the adoption of a drug policy. Within the region, many of Bangladesh's neighbours – India, Pakistan and Sri Lanka – tried during the 1970s to introduce changes in drug procurement and use in order to save money and improve therapy. Those efforts were met with opposition from the pharmaceutical industry and from governments of countries where the major drug-producing companies are headquartered.[13]

Similar difficulties occurred within Bangladesh. In 1974 an attempt was made to introduce centralised buying of drugs from the cheapest sources; in 1978 a list of essential drugs could not be widely applied and new drug legislation could not be enacted 'due to persistent opposition from interested quarters'.[14]

As one leading researcher on pharmaceutical policy has recently pointed out:

> A country's pharmaceutical and health policy cannot be isolated from its general development strategy. Good health depends on many factors and health services and drugs play only a limited part in improving health. A national development strategy aimed towards improving people's living conditions and, therefore, their health requires economic growth and its equitable distribution. This in turn depends not only on national factors but, perhaps more importantly, on international economic, financial and political conditions, which the developing world is often unable to affect. Ultimately, then, a country's pharmaceutical policy is open to manipulation by international influences, especially if the country is heavily dependent on aid....[15]

In the light of these potential obstacles, it was all the more remarkable that Bangladesh was able to develop and introduce a drug policy. Part of the credit goes to the dedication of the eight-person Expert Committee that drew up the policy in the space of two weeks in April 1982. Described by the director of a large Bangladeshi NGO that is engaged in many aspects of health care as 'a group of professionals whose technical competence was without doubt', the committee drew up a list of 16 criteria for evaluating drugs that were based on the most up-to-date scientific information available. National Professor

Nurul Islam, who was Chairman of the Expert Committee, described this as 'rare for a developing country. Usually the information available is years out of date – not just one or two years – but several.'[16]

The main objectives of the NDP were to:

- ensure increased availability and accessibility of good quality essential drugs;
- eliminate useless, non-essential and potentially hazardous drugs from the market (this was taken to include allopathic, homeopathic, and traditional Ayurvedic and Unani medicines);
- encourage local manufacture of drugs and raw materials, particularly essential drugs;
- develop appropriate legislative and administrative mechanisms; and
- take gradual steps to manufacture, distribute and sell drugs by their generic names.

In addition, the Drugs (Control) Ordinance provided the legislative framework that allowed the government to fix maximum prices for the import or sale of raw materials and for the retail sale of finished drugs. It also required that registered pharmacists were to oversee the production and sale of all allopathic drugs, and that manufacturers had to follow Good Manufacturing Practice or their production licence could be revoked. Strict penalties were spelled out in the Ordinance for the manufacture or sale of substandard drugs, in an attempt to enforce quality requirements.[17]

The two major immediate effects of the NDP related to the selection of essential drugs and to the banning of 1,666 products that were useless, ineffective or harmful. The essential drugs consisted of 150 substances that were designed to meet most therapeutic needs in the country, plus a supplementary list of 100 drugs for specialised use. Of the 150, 12 were identified for use by health workers at village level and a further 33 for use up to the sub-district level (thana or upazila), with the remainder for use up to the tertiary level. (At present there are 302 drugs, 15 used at village level and a further 58 at sub-district level.)

These two aspects provoked most of the controversy which greeted the introduction of the NDP. Members of the medical profession objected to being told what drugs they could prescribe, while the pharmaceutical industry objected to being told what drugs it could produce and sell.

Nonetheless, the pharmacological principles of the NDP were sound and even

today are still in line with the most authoritative advice available anywhere in the world. They also helped to achieve many of the major objectives of the NDP: a focus on essential, safe, effective products and the elimination, where possible, of products more likely to cause harm or to divert attention and resources away from real therapeutic needs. As WHO points out:[18]

> The selection of essential drugs to meet the health needs of the population is an important part of a national drug policy.

A staff member of WHO's Action Programme on Essential Drugs summarises the clear advantages of appropriate drug selection:[19]

- Reduction in the number of products to be purchased, analyzed, stored, distributed; (in other words ease in logistics);
- Improvements in the standards of use of drugs, management, monitoring of drug usage (to know which drugs are used where and how);
- Improvement of information on drugs and training;
- Easier recognition of adverse reactions in populations using relatively few drugs.

In other words, therapy improves and costs (both social and economic) can be kept down or more medicines can be supplied for the previous price.

Dr. Humayun K.M.A. Hye, former Director of the Drug Administration and one of the members of the Expert Committee, made the point more sharply, when he said in the early 1980s, 'Inadequate resources should not be wasted on drugs that are irrelevant or of marginal usefulness, while millions are dying without health care, deprived of live-saving drugs'.[20]

Praise and criticism

Shortly after the Bangladesh National Drug Policy was introduced, the Asian Development Bank commented: 'The efforts to make better use of existing resources through adoption of the new drug policy and through attempts to produce essential drugs locally are steps in the right direction.'[21]

Dr Halfdan Mahler, then Director-General of WHO, used his attendance at a regional meeting of health ministers in Dhaka in September 1982 as the opportunity to congratulate Bangladesh on 'its courage in starting to put its drug house in order'.[22]

However, criticism of the policy was also strong. The pharmaceutical industry association – Bangladesh Aushad Shilpa Samity (BASS), which represents most

pharmaceutical companies (including multinationals) operating in the country – launched an advertising campaign against the policy under the headline: 'Crisis in drug industry – conspiracy against nation's drug industry must be thwarted'. The Bangladesh Medical Association (BMA), although agreeing to the objectives of the policy, objected to the way it was introduced and to the lack of official BMA representation on the Expert Committee. A former secretary-general of the BMA argued that doctors are the best judges of which drug is most appropriate for a particular patient.[23]

These negative reactions to the NDP were predictable and were part of the reason why official representatives of the BMA and of the pharmaceutical industry were left off the Expert Committee. It was felt that their participation would have only weakened or delayed, perhaps terminally, the NDP. Today, with the benefit of hindsight, some members of the former Expert Committee wonder if it was a wise decision. Certainly, in the short term, the speed of drafting the policy and the unanimity of the committee meant that it was a coherent document that had a group of strong advocates for it. In the long term, however, the discontent of the medical profession and of the industry has served to act as a continuing source of dissension which has helped to undermine belief in and support for the policy. This has created a climate where supporting the policy could be seen as being politically and sometimes personally risky. One result is that not enough effort has gone into the implementation of the policy over the years.

Another problem is that there has been little opportunity for reasoned discussion about the benefits and disadvantages of the NDP. This has meant that the tension between Bangladesh's health needs and the needs of the country's commercial interests remains a thorny issue and has been largely unresolved. This tension is a universal one and is only likely to be minimised through discussion, negotiation and compromise.

When the NDP was launched in 1982, a martial law administration was in power. Debate and discussion were not regular occurrences. Ten years later, an elected government is embarking on the difficult path towards consensus democracy. It has appointed a committee to review the NDP – a committee whose composition reflects many of the key actors in the drugs debate: the pharmaceutical industry, the BMA, the pharmacists, the dispensers, medical practitioners from several disciplines, politicians and government officials. The voice of the patients or consumers is strangely missing. Nonetheless, the discussion is underway. Achieving a balance between the commercial and health needs is the major challenge, not just for the review committee, but over the next 10 years and beyond, for the people of Bangladesh.

References:

1. Azad Chowdhury, A.K., Choudhury, S.A.R. and Das, A.M. (1990). *Regulatory Approaches to Rational Drug Use* (mimeo). Dhaka, p. 1
2. Berg, A. (1973). *The Nutrition Factor: its role in national development*. Washington: Brookings Institution
3. Khan, M.R. (1988). see ref:2 for details. *Evaluation of Primary Health Care and Family Planning Facilities and Their Limitations* Specially in the Rural Areas of Bangladesh. Dhaka: Bangladesh Institute of Development Studies, p. 175
4. UNDP (1991). *Human Development Report 1991*. New York: Oxford University Press
5. Hossain, H., Dodge, C.P. and Abed, F.H. (eds). (1992). *From Crisis to Development: Coping with disasters in Bangladesh*. Dhaka: University Press Limited, p. 198
6. Chetley, A. (1990). *A Healthy Business? World health and the pharmaceutical industry*. London: Zed Books, pp. 5-6
7. Khan, M.R. (1988). *op cit. p.* 23
8. Commission on Health Research for Development (1990). *Health Research: Essential link to equity in development*. New York: Oxford University Press, p. 40
9. Government of Bangladesh (1982). *Drug Policy of Bangladesh*. Dhaka: Ministry of Health and Population Control, p. 2
10. WHO (1977). *The Selection of Essential Drugs*. Technical Report Series No. 615. Geneva: WHO

    The most recent revision was in November 1991 and was reproduced in *WHO Drug Information*, Vol. 5, No. 4, 1991
11. von Wartensleven, A. (1983). 'Major issues concerning pharmaceutical policies in the Third World', *World Development*, Vol. 11, No. 3, p. 171
12. WHO (1991). 'Why countries need a national drug policy', *Essential Drugs Monitor*, No. 12, p. 1
13. Rolt, F. (1985). *Pills, Policies and Profits*. London: War on Want, pp. 70-2
14. Chetley (1990). op cit. pp. 95-6
15.. Kanji, N. (1992). 'Action at country level: the international and national influences' in *Drugs Policy in Developing Countries* (Kanji, N., Hardon, A., et al) London: Zed Books
16. Chetley (1990). op cit. p. 98
17. Government of Bangladesh (1982). *The Drugs (Control) Ordinance*, 1982. Dhaka: Government of Bangladesh
18. WHO (1988). *Guidelines for Developing National Drug Policies*. Geneva: WHO

19. Helling-Borda, M. (1985). *Drug Selection, A Way to Better Therapy?* (DAP/85.2) Geneva: WHO

20. Chowdhury, Z. and Chowdhury, S. (1982). 'Essential drugs for the poor: myth and reality in Bangladesh', *Ecodevelopment News*, No. 23, (December), p. 43

21. From a report by the Asian Development Bank in November 1983 appraising the health and family planning situation in Bangladesh, cited in: Rolt (1985). op cit. p. 14

22. Rolt (1985). op cit. p. 90

23. Chetley (1990). op cit. p. 99

CHAPTER 1

The Success of the Drug Policy

A YOUNG WOMAN, barely more than a girl, carries a tiny thin baby on her shoulder and waits on the central divider at a major intersection for the traffic light to change to red. That is her cue to walk up and down the line of rickshaws, baby taxis, cars, trucks and buses, hand outheld, dark eyes pleading for a few Taka to feed herself and her child. At every intersection in Dhaka, the scene is repeated by others whose only source of livelihood is the compassion of a passerby.

For children especially, life is tough in Bangladesh. More than 875,000 children under five years of age die each year – about 100 an hour.[1] Children under five make up less than 15% of the population but account for 45% of deaths. A major cause of childhood deaths is dehydration from diarrhoea. In 1981, before the NDP was introduced, the use of oral rehydration therapy – an idea which was actually developed in Bangladesh – was not widespread. Instead, a variety of so-called antidiarrhoeal products were on the market which did nothing to combat the dehydration. One effect of the NDP was to remove virtually all of these preparations. Only loperamide (for use at the tertiary level) and oral rehydration salts (ORS) are now included in the country's essential drug list. The consequence has been that in dispensaries, hospitals and with prescribers, the use of ORS has increased considerably.[2]

Focusing attention on the most essential medicines by means of the withdrawal of the ineffective or useless products was one of the major objectives of the NDP. A leading paediatrician in Bangladesh says that the banning of the ineffective antidiarrhoeals and a range of multivitamins and tonics for children has not caused any problems in treating children's illnesses. On the contrary, he says that many of his colleagues have now forgotten most of these products and are finding that they have the right drugs to treat their patients effectively.

Nobody could reasonably claim that "the more drugs, the better". National lists containing thousands of drugs have no advantage over more limited lists.

– Daphe Fresle
WHO Action Programme
on Essential Drugs
April 1992

As National Professor Nurul Islam, Chairman of the former Expert Committee that drew up the NDP, points out:[3]

> In a developing country like Bangladesh, the only way to make appropriate medicine reach people is to take inappropriate medicines away from them. And the only way of taking away bad medicines is to eliminate them.

Increased production of essential drugs

In fact, over the past 10 years, there has been a tremendous change in the nature of the pharmaceutical market in Bangladesh. First of all, as Table 1 shows, the value of local production of drugs has increased from 1,730 million Taka in 1981 (US$106.4 million at 1981 exchange rates) to 5,500 million Taka in 1991 (US$156 million at 1991 exchange rates). In local currency terms this represents an increase in the value of production of more than 217%.

At the same time as local production has increased, there has been an even more important increase in the production of essential drugs. According to the Expert Committee that drew up the NDP, nearly one-third of the money spent on drugs in 1981 went on 'unnecessary and useless medicines such as vitamin mixtures, tonics, alkalisers, cough mixtures, digestive enzymes, pal-

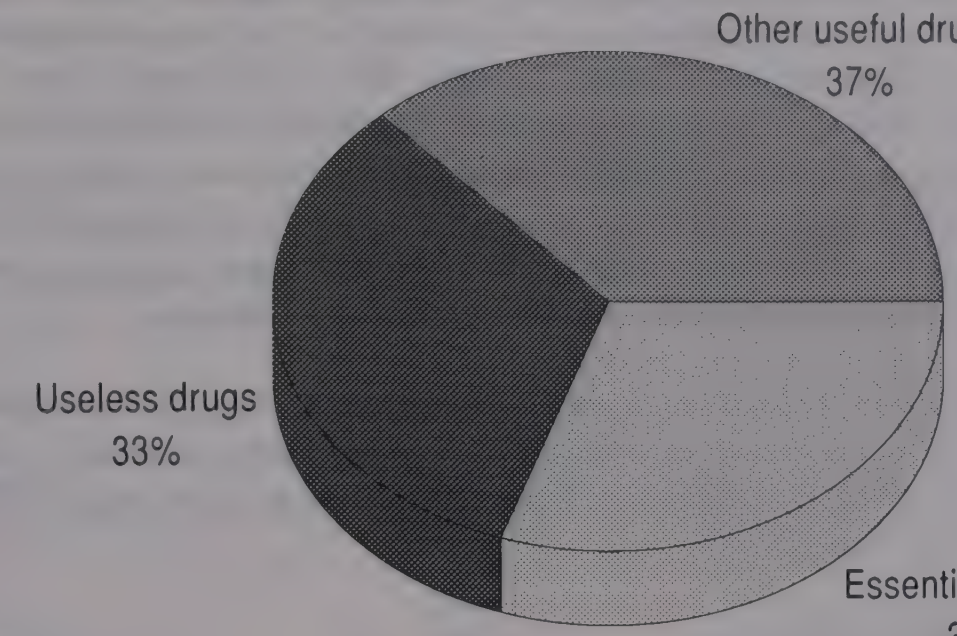
Table 1: Local production of drugs in Bangladesh (1981-1991)

Year	Local Production Total		by local company		by share of PHC/ED*		Annual increase in production % based on:	
	Tk. m	US$ m	Tk. m	%	Tk. m	%	Taka	US$
1981	1730	106.4	613	35.4	525	30.3		
1982	2160	107.6	842	39.0	751	34.8	24.9	1.2
1983	2260	97.9	1160	51.3	1168	51.7	4.6	-9.0
1984	2830	113.7	1470	51.9	1831	64.7	25.2	16.1
1985	3283	126.5	1864	56.8	2120	64.6	16.0	11.3
1986	3500	117.1	2080	59.4	2393	68.4	6.6	-7.4
1987	4048	132.2	2315	57.2	2955	73.0	15.7	12.9
1988	4383	140.3	2944	67.2	3390	77.3	8.3	6.1
1989	5000	155.0	3008	60.2	3887	77.7	14.1	10.5
1990	5300	161.1	3429	64.7	4370	82.5	6.0	3.9
1991	5500	156.0	3375	61.4	4400	80.0	3.8	-3.2

**PHC/ED = essential drugs needed for primary health care; for the years 1981 to 1987, this involved 45 drugs, from 1987 onwards, it involved 73 drugs (estimated for 1991)*

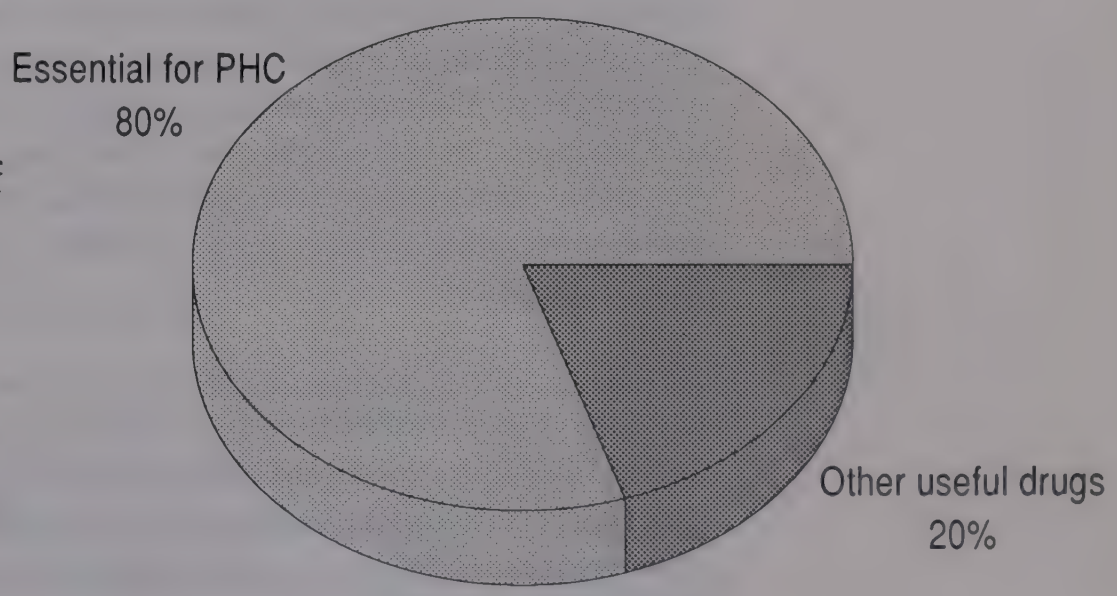
Source: Drug Administration, 1992

Figure 2: From useless to essential drugs

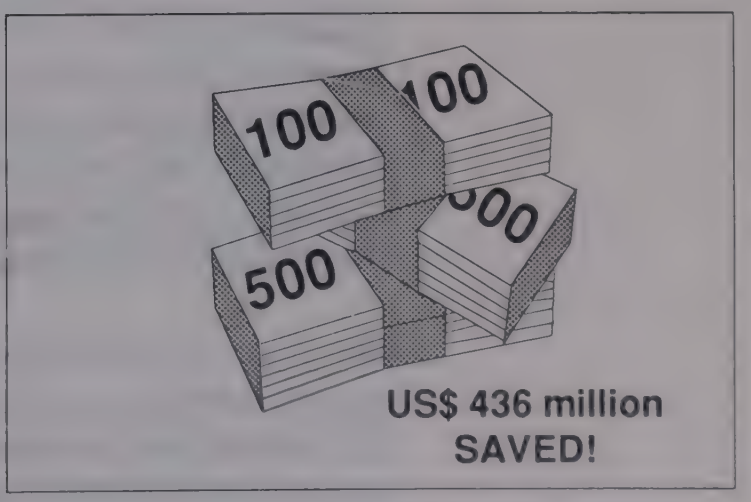


In 1981, one-third of local production was devoted to useless, ineffective or harmful products.

By 1991, as a result of the National Drug Policy, 80% of local production was directed towards Essential Drugs for Primary Health Care.



If there had been no National Drug Policy, and if the amount of useless products that were being produced had continued, then over the past 10 years, the people of Bangladesh would have wasted nearly US$ 436 million.



liatives, gripe water, and hundreds of similar products'.[4] As a consequence, only 30% of local production was devoted to the manufacture of the 45 essential drugs needed for PHC. By 1991, 80% of local production was concentrated on the drugs needed for PHC.[5] As Figure 2 indicates, this transformation from a high percentage of useless products to an emphasis on essential products has meant that over the years, the people of Bangladesh have been getting more of the drugs they need and have not been wasting their money on products that simply divert attention from real therapy.

Dr. Humayun K.M.A. Hye, former Director of the Drug Administration, has described the increase in essential drugs production as 'the number one achievement of the drug policy. In most developing countries you will not see a picture like this.'[6]

Stable drug prices

Increasing the availability of essential drugs is one part of the equation towards improved access. However, the drugs need to be affordable. Before the introduction of the NDP, because drugs were considered to be essential commodities, their maximum retail prices (MRP) were fixed by the Ministry of Commerce in consultation with the Drug Administration. After the NDP, this power was transferred to the then Ministry of Health and Family Planning and a committee was set up to develop a system for deciding on how to determine prices.

At the root of the pricing mechanism was the raw material price. Prior to the NDP, there was very little control over raw material prices. Occasionally, the Drug Administrator would intervene with an individual company and suggest that raw materials could be purchased at lower prices and, if the negotiation was successful, the savings might be passed on to the consumers. The Drugs (Control) Ordinance, however, set up the mechanism for the Drug Administration to approve the importation of raw materials and approve the price for imported or locally purchased raw materials. Table 2 shows the impact of this measure on the price of some of the most important raw materials. A spokesperson for one of the Bangladeshi companies said that it was 'good that transfer pricing was well controlled' and a representative from one of the multinational companies added that the control over the raw material prices 'has been good for the country'.

The dramatic reduction in raw material prices has come about because manufacturers are now required to purchase raw materials from internationally competitive sources. In the past, multinational companies and local companies operating under licence agreements with foreign companies were often tied to purchasing raw materials from a parent company or the licence

Table 2: Reduction in prices of some essential raw materials
(1981 to 1991)

Raw material	(Prices in US$/kg) 1981	1991	% reduction
Amoxycillin trihydrate (local)	130	112	13.8
Ampicillin trihydrate (local)	120	102	15.4
Cloxacillin	95	70	26.3
Doxycycline	1500	78	94.8
Frusemide	703	70	90.0
Glibenclamide	2350	180	92.3
Hyoscine butylbromide	1358	390	71.3
Ibuprofen	32	16	50.0
Levamisole	128	31	75.8
Mebendazole	287	19	93.4
Metroclopramide	200	105	47.5
Metronidazole	56	17	69.6
Oxytetracycline	54	16	70.4
Propranolol (local)	490	25	94.9
Rifampicin	473	178	62.4
Sulphamethoxazole	37	14	62.2
Tetracycline HCl	64	24	62.5
Trimethoprim	60	33	45.0

(local) = the raw material is now produced within Bangladesh
Source: Drug Administration

holder. For the foreign company, this had the advantage of transferring capital and profit out of Bangladesh. The pharmaceutical industry has a long history of this type of 'transfer pricing' throughout the world. Countries as diverse as Colombia, Brazil, the USA, the UK, the European Community, and Sri Lanka are among those that have tried to curb this practice over the years.[7]

Retail prices, too, have been held down. Table 3 gives the change in retail price of 25 major drugs between 1981 and 1991-2. Although there has been an average increase in the price of these products of 20% when the Taka price is considered, there is a decline of more than 40% when the prices are converted to US dollars to take into account some of the inflationary effects. This clearly has been one of the successes of the NDP.

This compares well with the pattern of change in the trade price of key essential drugs in an industrialised country such as the UK. Table 4 gives an indication of the changes that have occurred in prices of 17 products. In local currency terms (the pound), these products have increased by an average of

Table 3: Change in retail prices of 25 important drugs (1981- 1991/2)

Product	Retail price in Taka		Change	Retail price in US$		Change
	1981	1991-2	%	1981	1991-2	%
Amoxycillin capsule 250mg	2.50	2.90	16.0	0.15	0.08	-46.5
Ampicillin capsule 250mg	1.70	2.50	47.1	0.10	0.07	-32.2
Ampicillin syrup 60ml	21.00	33.00	57.1	1.29	0.94	-27.5
Antacid tablet	0.30	0.50	66.7	0.02	0.01	-23.1
Aspirin tablet	0.10	0.44	340.0	0.01	0.01	103.0
Atenolol tablet 100mg	6.00	3.30	-45.0	0.37	0.09	-74.6
Chlorhexidine sol. 112ml	10.53	16.68	58.4	0.65	0.47	-26.9
Chloroquine tablet 250mg	0.39	1.00	156.4	0.02	0.03	18.3
Cimetidine tablet 200mg coated	2.00 a	1.45	-27.5	0.08	0.04	-51.0
Cloxacillin capsule 500mg	3.60 b	5.65	56.9	0.14	0.16	11.0
Cotrimoxazole tablet	2.00	0.65	-67.5	0.12	0.02	-85.0
Dapsone tablet 100mg	0.20	0.16	-20.0	0.01	0.00	-63.1
Diazepam tablet 5mg	0.30	0.20	-33.3	0.02	0.01	-69.2
Fluocinolone cream 5g	12.00	26.00	116.7	0.74	0.74	-0.1
Frusemide tablet 40mg	0.60	0.50	-16.7	0.04	0.01	-61.6
Levamisole syrup 30ml	13.00	9.35	-28.1	0.80	0.27	-66.8
Levamisole tablet 40mg	1.30	0.41	-68.5	0.08	0.01	-85.5
Mebendazole tablet	2.11	0.70	-66.8	0.13	0.02	-84.7
Metronidazole tablet 200mg	0.70	0.63	-10.0	0.04	0.02	-58.5
Oxytetracycline capsule 250mg	1.05	1.00	-4.8	0.06	0.03	-56.1
Paracetamol tablet 500mg	0.25	0.62	148.0	0.02	0.02	14.4
Propranolol tablet 40mg	1.00	0.32	-68.0	0.06	0.01	-85.2
Ranitidine tablet 150mg	3.00 c	2.05	-31.7	0.12	0.06	-49.7
Rifampicin capsule 150mg	5.18	3.50	-32.4	0.32	0.10	-68.8
Vitamin B complex tablet	0.74	0.42	-43.2	0.05	0.01	-73.8
Average change			20.0			-41.7

a) 1983 price; b) 1984 price; c) 1985 price
Source: Drug Administration, 1992

26.7% over a similar period of time. However, in US dollar terms, the prices have decreased by just over 8%. It is worth pointing out that these particular products are among those that have been on the market for some time and for which there are usually generic equivalents available – something which may tend to hold down these prices. If the entire range of products available on the UK market was surveyed, it would be relatively easy to demonstrate that the total expenditure on medicines was increasing rapidly, largely due to the high costs of many of the newer products.

Table 4: Change in price of 17 major products in the UK (1980-1991)

Generic name	Brand name	Formulation	Price in £		Change	Price in US$		Change
			1980	1991	%	1980	1991	%
amoxycillin	Amoxil	100x250mg cap	12.47	17.48	40.1	29.06	29.45	1.4
ampicillin	Penbritin	100x250mg cap	25.21	7.32	-71.0	58.74	12.34	-79.0
betamethasone	Betnelan	100x500mg tab	4.00	3.65	-8.8	9.32	6.15	-34.0
chloroquine	Avloclor	500x250mg tab	3.75	17.50	366.7	8.74	29.49	237.5
chlorpheniramine	Piriton	50x4mg tab	0.45	0.48	5.6	1.05	0.80	-23.7
clofibrate	Atromid-S	50x500mg cap	1.62	2.09	29.0	3.77	3.52	-6.7
cloxacillin	Orbenin	100x250mg cap	14.80	18.20	23.0	34.48	30.67	-11.1
doxycycline	Vibramycin	10x100mg cap	5.48	5.23	-4.7	12.77	8.80	-31.0
fluocinolone	Synalar	1x5gm cream	0.30	0.26	-13.3	0.70	0.44	-37.3
frusemide	Lasix	25x2ml amp	6.46	6.50	0.6	15.05	10.95	-27.2
griseofulvin	Fulcin	100x125mg tab	1.90	3.15	65.8	4.43	5.31	19.9
imiprimine	Tofranil	100x25mg tab	3.25	1.65	-49.2	7.57	2.78	-63.3
iron dextran	Imferon	100x2ml amp	41.58	67.00	61.1	96.88	112.90	16.5
oxytetracycline	Terramycin	100x250mg cap	5.19	3.43	-33.9	12.09	5.78	-52.2
primidone	Mysoline	100x250mg tab	0.88	1.80	104.5	2.05	3.03	47.9
propranolol	Inderal	250x10mg tab	3.92	2.25	-42.6	9.13	3.79	-58.5
salbutamol	Ventolin	100x2mg tab	1.35	1.10	-18.5	3.15	1.85	-41.1
Average change:			26.7			-8.3		

Exchange rates: 1980 £1=$2.33; September 1991 £1=$1.685

Sources: UK Chemists and Druggists Price List, *Feb 1980, cited in: Melrose, D.*, Bitter Pills, *Oxford: Oxfam, 1982, pp216-17; BMA and the Royal Pharmaceutical Society of Great Britain*, British National Formulary, *London: BMA and The Pharmaceutical Press, No 22, Sep 1991*

In Bangladesh, there seems to be a definite link between the decline in retail and raw material prices. Of the drugs listed in Tables 2 and 3, eight are common to both. A comparison of the percentage reduction in the price of the eight raw materials and the corresponding dosage forms is given in Table 5. Statistical analysis shows that there is a strong positive linear association between the reduction in raw material and retail prices.

Even taking into account only the change in the retail prices expressed in Taka, when comparing this to the general consumer price index and the increase in costs of basic foods such as rice and fish, it becomes evident (as Figure 3 shows) that in real terms over the past decade, drugs have become more accessible and affordable to people in Bangladesh.

Bangladeshi companies gain a bigger share

Another transformation has been the growth of the national industry. In 1981,

Table 5: Comparison of the reduction in prices of eight raw materials and corresponding dosage forms (1981-1991/92)

Drug	Percentage reduction	
	raw material price	retail price
Amoxycillin	13.8	46.5
Ampicillin (capsule)	15.4	32.2
Ampicillin (syrup)	15.4	27.5
Cloxacillin*	26.3	11.0 [increase]
Levamisole (syrup)	75.8	66.8
Levamisole (tablet)	75.8	85.5
Metronidazole	69.6	58.5
Oxytetracycline	70.4	56.1
Propranolol	94.9	85.2
Rifampicin	62.4	68.8

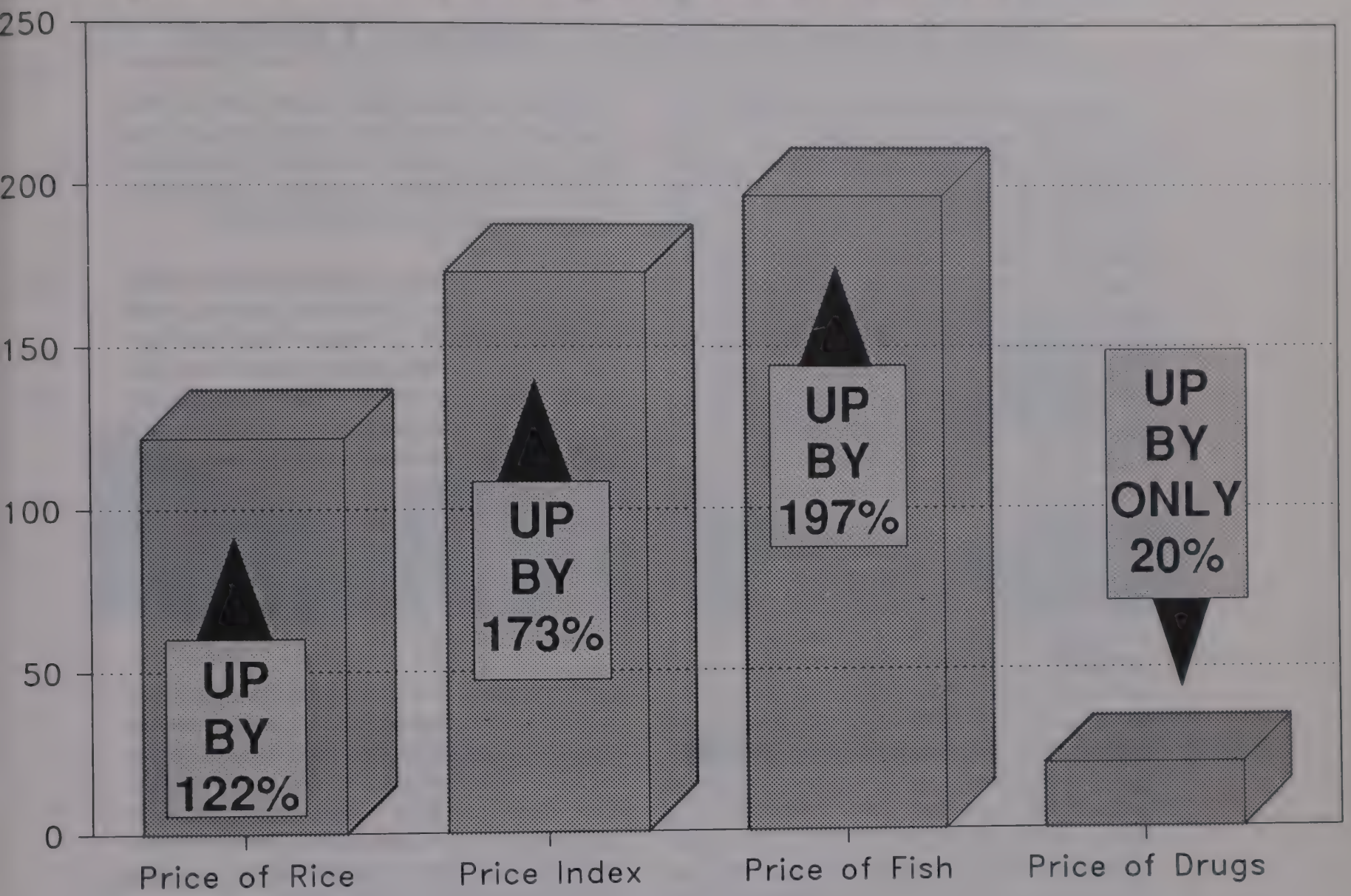
** The retail price of cloxacillin increased by 11 per cent.*
The correlation coefficient (r) between the percentage reduction in raw material prices and the percentage reduction in the retail price of corresponding formulations is equal to 0.79.

Table 6: Gross sales turnover of leading companies (in millions of Taka)

	Company	Country of origin	1981	1988	1989	1990	1991	Market Share %
1	Square	Bangladesh	70	540	610	720	850	15.5
2	Opsonin	Bangladesh	<50	310	430	490	540	9.8
3	Beximco	Bangladesh	<50	250	310	415	502	9.1
4	Fisons	UK	140	337	375	430	500	9.1
5	Pfizer	USA	200	263	270	300	350	6.4
6	Glaxo	UK	110	322	310	350	340	6.2
7	Acme	Bangladesh	<50	145	195	240	300	5.5
8	BPI/Rhone Poulenc	France	120	201	215	220	260	4.7
9	EDCL	Bangladesh		267	340	155	245	4.5
10	Hoechst	Germany	115	190	180	185	220	4.0
11	Ciba-Geigy	Switzerland		105	150	180	200	3.6
12	Organon	Holland	50	115	165	180	187	3.4
13	ICI	UK	50	85	97	126	167	3.0
14	Squibb*	USA	64	110	120	105	105	1.9

**Squibb ceased trading in October 1991*
Sources: Drug Administration, 1988 and 1992; Essential Drugs Company Limited annual reports for 1988-89 and 1990-91

Figure 3: Percentage change in prices 1981 to 1991



eight multinational companies controlled 65% of the local production and about 75-80% of total sales, including about 80% of sales to the government sector.[8] By 1991, Bangladeshi companies controlled more than 60% of the local production, and the five leading Bangladeshi companies accounted for about 45% of total sales. The top three companies are now Bangladeshi firms (see Table 6 on opposite page), and one company – the government-owned Essential Drugs Company Limited (EDCL) – supplies about 70% of the drugs for the government health services. EDCL's Managing Director, Md. Anisul Islam, says proudly that 'EDCL helped in the success of the Drug Policy and we are also a result of the Drug Policy'. EDCL's achievements are described in Box 3 on next page.

Decreasing dependency on imported drugs

The growth of national companies and the overall growth of local production

3. The Essential Drugs Company Limited

The Essential Drugs Company Limited (EDCL) came into existence in 1983, but it was preceded by the Government Pharmaceutical Laboratory which was a project started in 1962 under the then Ministry of Health and Family Planning. Later renamed the Pharmaceutical Production Unit (PPU), its objective was to manufacture and supply essential drugs to government hospitals and clinics. However, the PPU suffered from a lack of business expertise and, for many years, functioned at well below its potential capacity. In 1983, it was decided to expand the operation and establish it as a limited company, with the shares owned by the government.

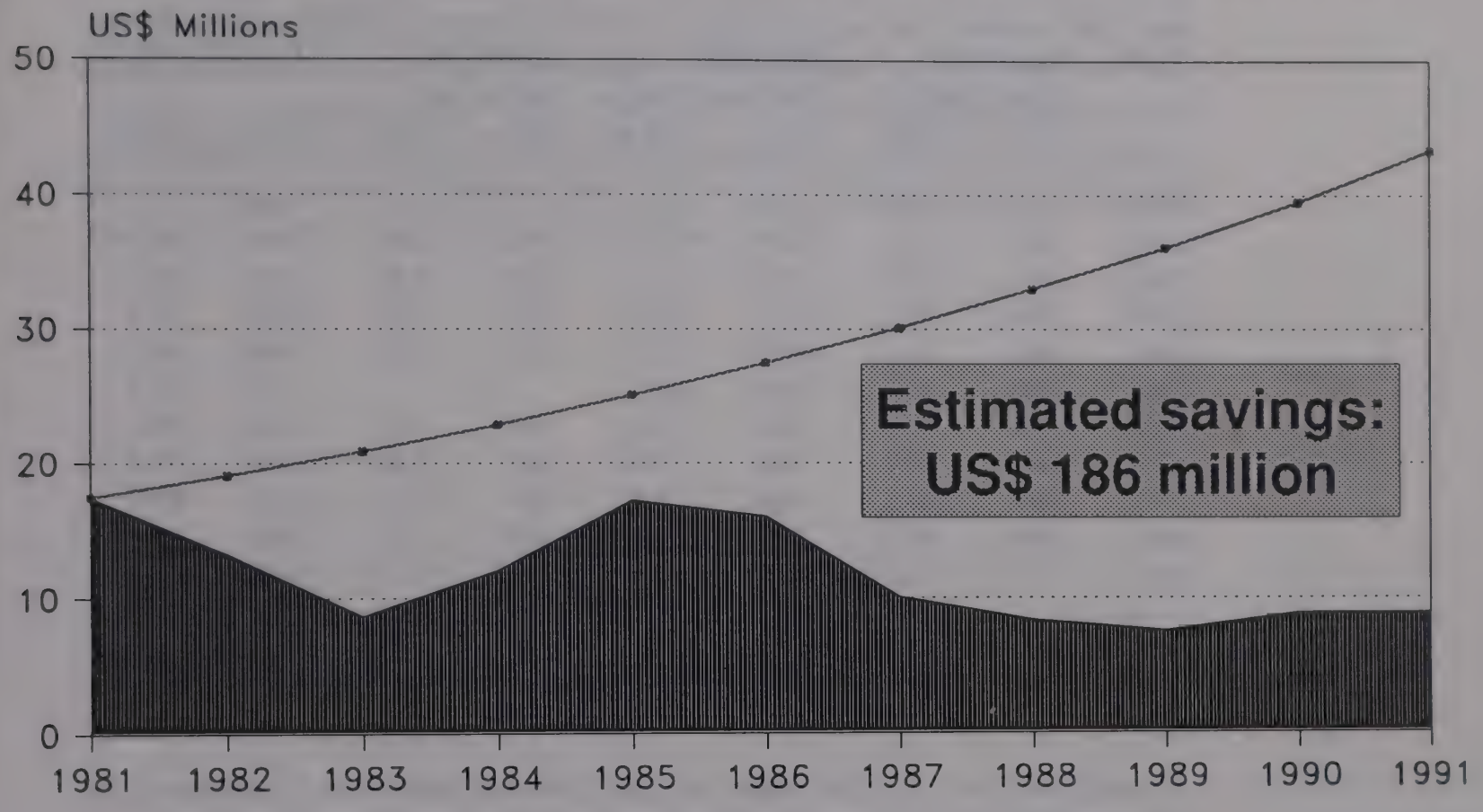
Since 1983, the company has expanded consistently. It now has two production facilities and produces more than 40 products in 60 formulations, compared to just 12 drugs when it started. Sales figures have also been going up, at least until 1989 when the government decided to decentralise purchasing of drugs for the health care system. Since then, instead of supplying to one client – the Central Medical Store – EDCL has to deal with more than 200 clients scattered throughout the country. This led to some confusion but the situation has now stabilised. Hospitals buy up to 70% of their requirements from EDCL. The company has also recently started selling to international agencies and NGOs in an effort to expand its sales base and ensure healthy growth.

EDCL's price for drugs is from 50 to 60% of the retail market price. This lower price is made possible thanks to an interest- free loan from the Asian Development Bank, cheaper premises than most other companies, equipment depreciation, large-scale production, no real promotion expenses and no need to pay a dividend to shareholders. The low price is also matched with high quality. According to Md. Anisul Islam, the company's managing director, EDCL pays careful attention to quality control throughout the entire production process.

EDCL has plans to expand, both in terms of new product lines and an additional plant to increase production capability. The possibility of setting up a raw materials plant is also being studied. The new product lines may be oral contraceptives and intrauterine devices (IUDs). In 1991, EDCL had a total staff of 442, of whom 254 were engaged in production.

has had another beneficial effect: fewer finished drugs now need to be imported into the country. 'Now only about 10-15% of medicines are imported, and these are only the high-tech ones, the ones that are too complex to make in this country,' says Brigadier Dr. Mukhlesur Rahman Khan, Director, Drug Administration. This has led to considerable savings in foreign exchange. Prior to the NDP, half the drugs considered essential for public health were not being manufactured in Bangladesh.[9] Today, although the total value of imports in the pharmaceutical sector has increased (see Table 7), the import of finished drugs has decreased significantly. In 1981 one-third of the import bill was for finished drugs, but in 1991, it was less than one-eighth. Similarly, the proportion of imports devoted to packaging material has dropped from

Figure 4: Estimated import savings as a result of Drug Policy



20% in 1981 to only 10% in 1991, whereas raw materials have increased from just under half to more than three-quarters of the import total.

The import statistics, however, do not show what might have happened if there had been no Drug Policy. If there had been no change in the structure of the market, and the dependence on imported drugs had continued over the past 10 years, an additional US$186 million would have been required to pay for the imports of finished drugs (see Figure 4).[10] In addition, before the NDP, the cost of the raw materials imported for the manufacture of useless and ineffective products constituted nearly 40% of the import liability for drugs.[11] If those products had not been banned, and if the import of raw materials to produce them had continued, then some US$155 million of valuable foreign currency would have been wasted.

Thus, over the past 10 years, the money spent on pharmaceutical imports has become better focused on the import of raw materials for essential drug

2559
DR-415

Table 7: Pharmaceutical sector imports (1981-1991)

Year	Import of Raw Materials		Import of Finished Drugs		Import of Packaging		Total Imports	
	Tk. m	US$ m	Tk. m	US$ m	Tk. m	US$ m	Tk. m	US$ m
1981	407	25.1	284	17.5	171	10.5	862	53.0
1982	487	24.3	270	13.5	132	6.6	889	44.3
1983	676	28.4	232	9.7	165	6.9	1073	45.1
1984	952	38.2	301	12.1	230	9.2	1483	59.4
1985	982	37.8	337	13.0	245	9.4	1564	60.2
1986	1291	43.2	482	16.1			1773	59.3
1987	926	30.2	310	10.1	118	3.8	1354	44.2
1988	1403	44.9	263	8.4	123	3.9	1789	57.2
1989	1468	45.5	244	7.6	330	10.2	2041	63.3
1990	1483	45.1	294	8.9	217	6.6	1994	60.6
1991	1978	56.1	315	8.9	265	7.5	2557	72.5

Note: Raw materials figure for 1986 includes packaging material
Sources: Drug Administration, 1992 and WHO (1988). World Drug Situation. *Geneva: WHO*

production. This, too, has been another factor in the effort to improve the availability and accessibility of essential drugs throughout the country.

An indirect effect of the NDP has been the increasing tendency of pharmaceutical companies – both national and multinational – to set up raw material production facilities within Bangladesh. As production and sales of drugs have increased over the years, companies have realised the advantages of having easier access to raw materials and of being able to use the sale of locally produced raw materials to supplement income from the wholesale or retail trade. By the end of 1992, there will be factories manufacturing amoxycillin, ampicillin, chloroquine, paracetamol, propranolol, sulphamethoxazole and trimethoprim. This has three possible benefits: it could help to decrease dependence on imported raw materials; it could increase the level of industrial development in the country; and it could help companies develop export potential by becoming acknowledged producers of quality raw materials.

National Professor Nurul Islam points out that the Bangladesh Drug Policy 'has been justifiably taken up as an example for Third World countries'. He said in 1989 that the 'progress and development in the pharmaceutical sector in Bangladesh during the past seven years indicate how effectively the WHO concept can be put into practice and local industries protected, provided there is a sound drug policy backed by political will'.[12]

But today there is still some simmering discontent within the industry, still some concern being expressed by the medical community. As three of Bangladesh's leading researchers and academics pointed out in 1990, the beneficial effects of the NDP are evident at the 'macro' or national level, but harder to quantify at the 'micro' level of the individual prescribers and consumers, or even among individual companies.[13] There is now little doubt or debate about the successes of the NDP, but its limitations are increasingly the subject of the current debate within the country.

References:

1. Mannan, M.A. (1990). *Interactions Between Infant Mortality and Fertility: a case study of Bangladesh*. Research Report No. 118, Dhaka: Bangladesh Institute of Development Studies, p. 2
2. UNICEF (1982). *Rational Use of Drugs in the Management of Acute Diarrhoea in Children*. Dhaka: UNICEF
3. Islam, N. (1989). 'Bangladesh National Drug Policy: an assessment', *Tropical Doctor*, Vol. 19, January, pp. 18-20
4. Government of Bangladesh (1982). *Drug Policy of Bangladesh*. Dhaka: Ministry of Health and Population Control, p. 1
5. In 1987, the number of drugs considered necessary for PHC was increased from 45 to 73 which could account for some of the increase; however, data from the Drug Administration in 1988 shows that, even before the change, essential drugs for PHC amounted to 75% of local production in 1987.
6. Chetley, A. (1990). *A Healthy Business? World health and the pharmaceutical industry*. London: Zed Books, p. 103
7. Ibid., pp. 22-5
8. Melrose, D. (1982). *Bitter Pills*. Oxford: Oxfam, p. 37
9. Government of Bangladesh (1982). op cit. p. 1
10. The estimated cost of finished drugs import requirements if there had been no Drug Policy is based on an annual increase of requirements plus an inflation increment totalling 9.5%
11. Hye, H.K.M.A. (1992). *Ten Years of the Bangladesh Drug Policy* (mimeo). Dhaka, p. 3
12. Islam (1989). op cit. pp. 18-20
13. Azad Chowdhury, A.K., Choudhury, S.A.R. and Das, A.M. (1990). *Regulatory Approaches to Rational Drug Use* (mimeo). Dhaka, p. 5

CHAPTER 2

The Policy Today

A SERPENTINE LAKE curves through the so-called residential area of Dhanmondi in Dhaka. At one time it was primarily residential, but now, although still containing some residents, it is better known as the location for offices of many non-governmental and international organisations working in Bangladesh. It is also the location for some commercial enterprises, including several pharmaceutical companies.

Late on a Thursday afternoon, as people streamed by on the main road on their way home to start the weekend, a few young boys ventured into the lake to bathe and to fish. Around the shore, a few adults sat in the shade, talking, watching, relaxing.

Across the water, behind some trees, a well-kept white building reflected the bright sunshine. A sharp-eyed observer might have spotted the small signpost on the road leading to the building that indicated simply: Ciba-Geigy. This was the Dhaka office of the Swiss-based chemical and pharmaceutical multinational.

Ciba-Geigy's presence in the Bangladesh pharmaceutical market is significant because the company opened a factory after the introduction of the NDP. To those who support the policy, this simple fact is an indication that the NDP has been good for business.

Not far from Ciba's office is the Dhaka office of Glaxo, a pharmaceutical company whose presence in Bangladesh dates back long before the NDP. Today, one gets an eerie feeling walking through the building. It is almost empty, with only a skeleton staff present. The major part of the staff has been moved to the factory site in Chittagong to economise on overhead costs. To

Policy development must start first. Without government understanding and support for improvements in drug supply, quality and use, the success of interventions will always be very limited. Second, and a close third, are interventions in supply and quality assurance. The fourth priority is to improve the rational use of drugs since this is, of course, dependent on a reliable supply.

– Dr Fernando Antezana, Director, WHO Action Programme on Essential Drugs, April 1992

those who are opposed to the NDP, this is a powerful symbol of the negative impact of the policy on the pharmaceutical industry in Bangladesh.

Neither of these images is completely accurate. They provide only a part of the message about the situation of the pharmaceutical industry in Bangladesh. Ciba's decision was one element of a long-term strategy, and was taken at a time when it appeared that the changes being introduced by the NDP would not affect the range of products that it planned to produce. Focusing only on the ghostly Glaxo office in Dhaka ignores the investment in a new antibiotic production facility, opened in July 1992, that the company added to its extensive factory in Chittagong. It also ignores the point, reported in the quarterly magazine of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), that Glaxo had 'faith in the future' of Bangladesh as a country in which to operate.[1]

Drug companies are in the money business. Why should we be complacent and think that they will look after our health?

– Director of a Bangladeshi NGO working in the health field, July 1992

Changing positions

Over the years, the industry in Bangladesh has taken different public positions about the Drug Policy. For the first four years, there was almost unanimous opposition, with constant warnings that the multinational companies would soon leave the country. In 1985, for example, the US Pharmaceutical Manufacturers Association (PMA) published a report that said foreign investors, not only in the pharmaceutical field, were withdrawing from Bangladesh. It said the NDP had 'left indelible scars on the country's image as a base for an attractive, safe, and reliable business community'.[2]

However by 1986, political expediency led the industry to praise the NDP in an open letter to the country's new Members of Parliament.[3] The Bangladesh Aushad Shilpa Samity (BASS) said that the NDP

> represents a philosophy whose scope extends beyond the need of today into realms of the future.... The ordinance has been applied, tested and has to its credit today, many examples of its beneficial aspects ... lower drug prices ... reduced dependence on the foreign imports ... better appreciation of the people's needs by the industries.... Drug Control Ordinance 1982 has benefitted not only the Pharmaceutical Industry but more the public at large.

Almost ritually since then, the BASS has taken out large advertisements in leading newspapers to protest against any attempts to implement the NDP more fully. A 1987 advertisement appealed to the government to 'Save the pharmaceutical industries from destruction', while a 1989 advertisement urged the government to 'Resist conspiracy against local pharmaceutical industry'.

With the change of government in 1990 and the move towards a more democratic society, the industry – and according to several sources, the multinational companies in particular – saw an opportunity to restart the debate about the NDP in the hopes of removing some controls. An attempt in 1990 by the former government to introduce a national health policy had infuriated the Bangladesh Medical Association (BMA) and the industry saw the chance to work with an old ally to introduce revisions to the Drug Policy.

Old arguments

Many of the arguments that were brought forward as ammunition against the NDP, however, were old and somewhat weary. The classic one, fueled by three recent events, was that foreign companies were leaving the country. The 'evidence' for this comes from the decisions by three multinational companies – Squibb, SmithKline and French (SKF), and ICI – to sell off their pharmaceutical subsidiaries in Bangladesh. It is a convenient argument, but one that is not altogether accurate, as Box 4 on page 38 shows. Perhaps more accurate is the comment made by one company executive: 'multinationals don't like being pushed into things'.

Another argument that has been around for 10 years is that drugs banned in Bangladesh are being smuggled across the border. The Foreign Investors Chamber of Commerce and Industry (FICCI) says that this smuggling of banned drugs has 'increased',[4] although a spokesperson for the FICCI admitted that there was no hard data to demonstrate an increase. 'It's the feeling we have based on monthly reports from company sales representatives.'

While it is clear that the smuggling of banned drugs (or the smuggling of any commodities – a practice that occurs with great regularity, and in both directions) is something that should be dealt with effectively, the fact that smuggling occurs is not a flaw in the Drug Policy. The solution rests in better enforcement by customs officials and the police, stiffer penalties for those caught and better education about which drugs are worth using. The answer is not to argue that it would be better to allow Bangladeshi companies to make these products, as has been done by several company executives and by the editor of *The Morning Sun* and *The Pulse* – two publications that have kept up a barrage against the Drug Policy. The editor, Anwarul Islam Bobby, says that drugs worth an estimated US$25-30 million a year were being smuggled into Bangladesh and being sold at five to six times this price.[5] He also says that our industries should have been making these products. Drug manufacturers agree with the estimate and suggest that if they were allowed to make the products, company revenues would be boosted by about US$20 million. Salman Rahman, recently elected President of BASS said, 'While affecting the

For the pharmaceutical industry, regulation is there and has to be there. It will differ from country to country, depending on the situation. The regulatory authority should be a powerful authority. The decisions should be clear cut and transparent. Having a drug policy does not have to be a major problem for the pharmaceutical industry. If it's good for the country, then we have to do it.

– Executive of a Bangladeshi company, July 1992

4. Is the Drug Policy chasing companies away?

In a recent letter[6] to the Minister of Health and Family Welfare, the Foreign Investors Chamber of Commerce and Industry (FICCI) – which represents 57 foreign companies operating in Bangladesh, including the pharmaceutical companies – said that the Drug Policy had 'crippled many pharma companies and particularly foreign investment in this sector'. The letter added that 'over-regulation, discrimination, inability to market research products, patent violations etc. have led to withdrawal of three out of nine multinational companies[7] and some more are contemplating it.'

This story has now been spread widely throughout the country. The industry, both local and multinational, many academics and physicians, and some of the media happily repeat it with confidence. But is it true? No, not entirely.

The three companies involved are SmithKline and French (SKF), Squibb, and ICI. Both SKF and Squibb have recently been involved in two of the biggest merger deals ever seen in the pharmaceutical industry: SKF joining with Beecham to form SmithKline Beecham and Squibb linking up with Bristol-Myers to form Bristol-Myers Squibb. In both cases the management of the newly-formed companies decided to consolidate holdings, sell off assets considered to be the least productive from a global perspective, and streamline the entire operation. Both companies decided they could easily dispense with their activities in Bangladesh without adversely affecting their global profits. Why? Let's put the pharmaceutical market in Bangladesh into perspective.

In 1991, the **total** sales of all medicines in Bangladesh amounted to an estimated US$165 million. That is:

- approximately 0.1% of the total world market for drugs;
- approximately one-half the amount any one major international company spends on the research and development of a new drug;
- approximately 0.5% of the amount the entire industry spends promoting its products globally each year.

Squibb's total sales in Bangladesh were only some US$3 million during its last full year of trading, while SKF's sales were around US$1 million. This represents about 0.06% of Bristol-Myers Squibb's global sales, and about 0.02% of SmithKline Beecham's – in both cases an insignificant amount.

ICI was not going through a merger. However, like many other large chemical companies, it has been adversely hit in recent years by a drop in sales. Internationally, the company also decided to streamline its operations and concentrate on the most profitable subsidiaries and the most profitable product lines. Although the Bangladesh subsidiary was showing good sales figures and a healthy profit, the total amount (just under US$5 million in sales) was too small for the international company to justify maintaining support for the subsidiary. So, it negotiated a sale to the local management that was very favourable to the company in Bangladesh, including an arrangement whereby the new local company – Advanced Chemical Industries, or ACI – would have exclusive rights for 10 years to import any of ICI's products that were not being produced locally. At the time, the business community in Bangladesh 'welcomed ICI's decision to sell its pharmaceutical formulation plant' to the local management team.[8] It was described by *The Daily Star* newspaper as 'a positive step on the part of a giant multinational to help a Third World country to indigenise an industry through complete transfer of technology, development of managerial skills in local staff and transfer of equity capital to local entrepreneurs.'[9] If the business community welcomed it one day, it can hardly use the sale as an indication of the need to change the NDP the next.

In all three cases, the global business recession, the need to consolidate operations and focus on major markets and products has been the overriding factor in companies' decisions to leave Bangladesh, not the Drug Policy. The problem is that Bangladesh has a small market, little industrialisation, and an unstable economy. As a representative from one multinational pharmaceutical company put it, 'Why should we buy problems in Bangladesh? We can get a better investment in Eastern Europe.'

local industries, the ban is only encouraging large-scale smuggling of these items, depriving the country of huge revenue.[10]

These are powerful arguments if one ignores the nature of the products that are being smuggled. One of the more lucrative products is a cough medicine called Phensedyl that contains codeine (a potentially addictive opiate) and an antihistamine (that can have a sedating effect). Every investigation about the use of Phensedyl shows that it is not being used to treat cough, but as a drug of abuse. Even an article in one of Anwarul Islam Bobby's own papers makes the point that 'if the buying and selling of Phensedyl continues unabated, it will be detrimental for the whole nation'.[11] Having such products made by companies in Bangladesh will not lessen the danger; it might even increase the problem as the price would likely drop, making these products even more accessible.

Safety, efficacy and usefulness are key criteria

Related to the drug smuggling question are some newer arguments for Bangladesh, although they represent a familiar chorus sung by the pharmaceutical industry in other settings around the world. These deal with generally allowing more drugs to be sold through a less restrictive registration procedure and allowing more products onto the market that in most countries are known as over the counter (OTC) drugs – preparations that do not require a prescription.

The industry is arguing (via the FICCI)[12] that 'any medicine which is approved through certification by three developed countries as safe and effective, should be allowed to be manufactured/imported' in Bangladesh. This position completely ignores the aims and objectives of the NDP. The Drugs (Control) Ordinance specifically states that the Drug Control Committee (DCC) has the responsibility to recommend the registration of products on the basis of their 'safety, efficacy and usefulness'. The key word here is usefulness. This is the element that offers a degree of assessment as to whether a product actually fulfills a public health need in the country and does so more effectively, more safely or more inexpensively or conveniently than products already on the market. To rely only on safety and efficacy as determined by regulatory authorities in the industrialised countries is to ignore the way the regulatory process operates, as Box 5 on page 40 about the US Food and Drug Administration (FDA) approval system demonstrates.

Some emotive arguments are being used to justify relaxing the registration system or the criteria for drug selection. Both physicians and company executives argue that patients are being deprived of the latest life-saving innovative products that are being sold in other countries.

5. Does FDA approval imply everyday use for all?

The US Food and Drug Administration (FDA) is generally considered to be the most thorough in the world. If the FDA approves a drug for use, why should anyone else – either a government or an individual hospital or group of clinics – bother to assess the drug again? FDA approval (like that of many other strict drug regulatory authorities) certifies a drug as safe and efficacious for its labelled indication(s). It does not address the key issue, whether the drug is safer or more effective than other agents or whether it is appropriate for additional uses. A further consideration that is not addressed is whether the additional cost associated with possibly only marginal benefits can be justified in different situations.

Source: Rucker, T.D. and Schiff, G. (1990). 'Drug formularies: myths-in-formulation', *Medical Care*, Vol. 28, No. 10 (October), pp. 928-42

Brigadier Dr. Mukhlesur Rahman Khan, Director of the Drug Administration, says that nothing could be further from the truth. 'Anyone can apply to register new medicines. All they need to show is that the product is safe, effective and useful. It is not difficult to get a drug registered in this country. The fees are low for registration. If the fees were higher, the price of drugs would increase. If it's a new drug that is not produced locally, it can be imported. In some cases, we are even prepared to allow a staged manufacturing process. For example, the product can be formulated abroad, but only the final labelling has still to be done, and that is done here. We allow that as a way of encouraging companies to at least start the production process.'

'Even a product that has not been formally registered can be imported by a doctor or an individual for personal consumption, not for commercial use. This can be approved in one day. I simply issue a "no objection certificate" that states that the product will not be used for commercial purposes, that it will be used under medical supervision and that we do not take any responsibility for possible adverse drug reactions that might occur. So any new drug can be made available. And, of course, registration of these products is also possible, although most of the companies find that products aimed at small market niches are not profitable. But the system is there, including an appeal system.'

A spokesperson for the FICCI retaliates that the system may be there in theory, but in practice drugs are refused registration with no reason given or it can take as long as four years to get a drug registered. 'What does that mean? It means that when the approval process started, the product was near the beginning of its product life cycle. By the time it gets onto the market, which can take as long as two years after official approval, it will be at the end of its

life cycle.' This argument is really about economics, not health. The companies, particularly the research-based multinationals, want to get their products onto the market while the sales materials are current, and before competitors begin producing similar drugs or the product comes off patent and cheaper versions are available.

The problem is not so much the Drug Policy, but the process by which it is implemented. The reasons why drugs are refused registration are quite straightforward: safety, efficacy or usefulness have not been proven and, in most cases, it is one of the latter two points. The time lag in registration is not that long compared to the time taken in many industrialised countries. Applications to introduce additional formulations of a drug that is already on the market proceed quite quickly in Bangladesh. Indeed, the staff of the Drug Administration regularly assess these types of products and the Director is able to approve them. Most of the delay comes about when a company wants to introduce a therapeutic agent that has not been in the country before. Understandably, then the Drug Administration wants to collect and study carefully the available information on the product. In those cases, the DCC must also meet to give final approval and there can be occasional delays caused by the non-availability of some of the senior government officials to attend the meeting. Developing a more streamlined process and a more regular review of the products permitted on the market might be a way of resolving the concerns. This is in keeping with WHO's advice that an important objective of any drug policy is to:

> establish a drug supply system that satisfies the health needs of the community and at the same time can respond to the health needs of the individual.[13]

However, it is also worth bearing in mind that new drugs are not necessarily better. There may be adverse drug reactions that develop in specific patient groups that were not evident during the testing period.[14] They may also be more expensive without providing any additional significant therapeutic advantages. One doctor who is on the government committee to review the Drug Policy makes the point that it is always necessary to 'look at the balance between benefits and risks to decide whether we should allow a new product on the market.' That does not mean that the product should simply have unrestrained use. Some new drugs have only a limited need and should be kept in reserve for certain circumstances. This highlights the need to look at the balance between people's health concerns and the concerns of the pharmaceutical industry. In many cases, the rational use of a drug demands restraint and care; however, the most sensible commercial approach calls for

widespread and unrestrained sales. A former medical director of Squibb in the USA explained the commercial viewpoint clearly when he said:

> The incidence of disease cannot be manipulated and so increased sales volume must depend at least in part on the use of drugs unrelated to their real utility or need.[15]

No discrimination between the private and public sector

An argument that follows on from this, that is being expressed by some voices in the industry, is that limitations on products should only apply to the government health sector and that the private sector should be free of any controls on the drugs that can be sold. A former President of BASS, Dr. A.M.M. Khan, who is currently Vice-Chairman of the Bangladesh Pharmacy Council (BPC), is one such voice. He says that essential drugs should be used in the government medical centres, but private sector use should be up to the doctors. 'I don't believe in unnecessary drugs. Whatever my doctor writes, that is essential, that is life-saving for me.'[16] Interestingly, he later said that medical practitioners need training in writing prescriptions. 'I've seen cases where four out of every five prescriptions are wrong.' So perhaps, as Box 6 on page 43 suggests, the doctor does not always know best.

A leading researcher on national drug policies makes the point that:

> Policies applied only to the public sector rationalise but a tiny proportion of the drugs market; not only is the rest of the market exempted from these policies, but often, through various incentives and subsidies, encouraged to develop further.[17]

When Nigeria introduced an essential drugs list, there was opposition to applying it to both the public and private sectors. Nigeria's Minister of Health, Prof. O. Ransome Kuti, has a powerful answer to the pharmaceutical industry's argument that there should be a difference in the drugs supplied to the public and private sectors. He tells them:

> Drugs are meant for diseases not sectors. If you can demonstrate to me that the diseases affecting people in the private sector are different to those affecting the people in the public sector, we shall adjust the list accordingly. If you put all these drugs in the private sector, what is to stop the two becoming mixed? Anybody can just go to the private sector and order.[18]

In Bangladesh, there already is a mixture between the public and private sector. There is no neat distinction. Even at the prestigious Institute of Post-

6. Does the doctor know best?

The usual comments that emérge in opposition to any type of limited list of drugs, include statements that the list will interfere with clinical freedom, that every patient is unique and therefore depends on the skill and training of the physician or the specialist to diagnose the problem and prescribe the correct medication, and any committee that sets out a list probably won't have the practical experience in each of the sub-specialities to do it properly. In Bangladesh, this last point was succinctly expressed by one company official who said that 'the Drug Policy was produced in a vacuum. It was state of the art as far as the technical part went, but it did not have any internal understanding of our situation here. The Drug Policy was dumped on the country without realising what was going on at the grassroots.'

These are powerful and emotive arguments, but do they reflect reality?

An effective limited list of medicines is not a restriction on clinical freedom. Rather, it acknowledges the simple reality that each doctor prescribes not from the entire range of some 8,000 different chemical entities, but from a limited subset of perhaps 25 to 400 preparations. The central question then becomes whether a doctor's own personal list is more or less optimal than one prepared by a group of experts and peers.

In the same way, a good drug selection list coupled with a formulary that indicates recommended therapies for certain conditions helps to improve a doctor's ability to treat the patients who he or she diagnoses. The suggestion that doctors should embark down the path of uncontrolled experimentation to accommodate variable patient response is an invitation to irrational therapy. Drug manufacturers often exploit narrow differences in their products to carve out a share of a therapeutic market. This combination of poorly delineated clinical differences, and artificially created distinctions among similar drugs, represent two major ingredients facilitating irrational prescribing.

Source: Rucker, T.D. and Schiff, G. (1990). 'Drug formularies: myths-in- formulation', *Medical Care*, Vol. 28, No. 10 (October), pp. 928-42

Graduate Medicine and Research Hospital in Dhaka, patients have to go to the nearby private sector pharmacies to buy the medicines they need for their operations or for their therapy.

Self-medication and over the counter *(OTC)* products

Another approach to the private sector question comes from the industry argument that some 'home remedies' should be allowed that 'effectively relieve symptoms and provide comforts to people'. It says that such products are normally available in many countries over the counter, that is, without a prescription.[19]

Many of the products the industry hopes to get onto the market in this way are the 'unnecessary and useless medicines' that wasted people's money

before the NDP. This goes against both the spirit and the letter of the NDP and is certainly not in the best interests of public health in the country.

According to WHO:

> unrestricted availability ... of medicines for self-medication may result in their inappropriate use, delay in diagnosis, and waste of resources. Guidelines should therefore be developed and adopted to ensure that there is careful selection of drugs that are allowed to be sold without prescription for the short-term relief of symptoms when medical advice and accurate diagnosis are not required.[20]

One of the main constraints on rational drug use is the existence of large amounts of drugs not controlled by health workers. Studies from all over the world suggest that a substantial proportion of pharmaceuticals are purchased without a prescription.

– Najmi Kanji and Anita Hardon, co-editors of *Drugs Policy in Developing Countries*, 1992

In any event, the concept of self-medication and OTC products has a different meaning in Bangladesh. Virtually any product can be obtained without a prescription. This already complicates rational therapy. To compound this irrationality by adding yet more drugs – and drugs which have doubtful value and usefulness – would be a step backwards for the country. Improvements in public health, better primary health care, and solutions to the enormous health problems in Bangladesh are not going to be found through allowing another range of ineffective drugs back onto the market.

Economic realities

Why, if there are clear arguments against these proposals, does the industry persist with them? Much of the reason has to do with the confusion of the two perspectives of health and economics. The industry is arguing primarily from an economic viewpoint: it wants to inject some fast growth into the market, and sees a way of doing that through a liberalisation of registration. The countervailing arguments come from a health background. Within their respective contexts, both arguments make sense. The conflict occurs when their aims clash, when what stimulates a healthy industry does not improve people's health, or vice versa. And this conflict can also manifest itself in other ways as the incident of the World Bank's involvement in the debate illustrates (see Box 7 on page 45).

But is the industry in an unhealthy state at the moment? If, as was evident in the previous chapter, production has been growing, has not this been beneficial to the industry? The answers to those questions require a more careful look at the pattern of growth of the industry over the past 20 years. In the 1970s, production capacity more than trebled and by the beginning of the 1980s, annual growth in the pharmaceutical market was running at about 20%.[21] Although the 217% growth in local production from 1981 to 1991 suggests that the pace has been maintained, more careful analysis shows that the average growth was just over 15% for the first five years, but had dropped

7. The World Bank's surprising intervention

In April 1992, Abid Hasan, Chief of the World Bank's Industry and Energy Unit in Bangladesh, sent a letter to the Secretary of the Economic Relations Division of the Bangladesh Government that called for detailed changes in the country's National Drug Policy. The 'suggestions' contained in the letter bear a striking resemblance to the letter to the Health Minister from the FICCI. They include: use free sales certificates as the method of liberalising drug regulation, lift all controls on prices, remove the control over drug advertising, end restrictions on the choice of products foreign firms can manufacture, and remove the controls on the import of raw materials.

At the time, another section of the World Bank – the Population and Health Unit – was finalising agreement with the government on a major five-year programme that includes a significant element on the rational use of drugs. The proposal for the programme included a statement that the National Drug Policy should be supported through complementary activities that would encourage better use of drugs including more information and education.

The Population and Health Unit heard about the Industry and Energy Unit's letter by reading an article in *The Telegraph* newspaper. Following some internal discussion, and some general concern expressed by many of the international agencies and the donors supporting the Population and Health programme, Abid Hasan sent a second letter in June that toned down the first set of 'suggestions'. In the second letter, although the same suggestions were repeated, they were expressed in more reasoned terms, offering alternatives to outright removal of controls.

Nonetheless, although welcoming the change of tone, a spokesperson for a major donor agency said, 'there should have been a public denunciation of the position'. The newspaper report that the World Bank was siding with the pharmaceutical industry in putting pressure on the government to change the Drug Policy was never retracted.

Sources: Letters from Abid Hasan to the Economic Relations Division, Bangladesh Government, 27 April 1992 and 8 June 1992, and newspaper report: Naser, M. (1992). 'WB for decontrolling drug price, import of raw materials', *The Telegraph*, 23 May, pp. 1 and 12

to just under 10% for the last five, and in the last two years – between 1989 and 1991 – the average growth is under 5%. (See Table 1 on page 22.)

These are worrying trends, but do they have anything to do with the Drug Policy? The changes in the rest of the manufacturing sector in Bangladesh suggest that they do not. According to the World Bank, manufacturing growth from the mid-1960s to the end of the 1970s averaged 6.8% per year, whereas throughout the 1980s, it only averaged 2.4% per year.[22] The slowdown in pharmaceutical manufacture matches a similar slowdown in general production, which is also the case globally.

Looking at sales figures rather than production values, a slightly different picture emerges, as Table 8 indicates. Among the leading companies, average sales growth has been in double figures over the past four years, with the exception of EDCL in 1990 which experienced a huge drop in sales due to the reorganisation of the purchasing system for drugs in the government sector. These figures are based on gross sales which include excise charges that have to be paid to the government. The growth rate in net sales (after payment of excise charges) is estimated by one industry source at about 10-12% per year. Another industry source confirmed the figure as being about right, but claimed that sales, like production, are beginning to decline.

If the growth in both production and sales are slowing down, profit margins will also decline rapidly. According to one multinational company, this is already happening in Bangladesh. Over the past five years, this company had a cumulative profit of about zero; some years it made a small profit, other years a small loss. One company official warns: 'nobody's in business to run at a loss for a long time'.

Table 8: Annual growth in sales of leading companies (1988-1991)

Company	1988-89	1989-90	1990-91
	% change	% change	% change
Square	13.0	18.0	18.1
Opsonin	38.7	14.0	10.2
Beximco	24.0	33.9	21.0
Fisons	11.3	14.7	16.3
Pfizer	2.7	11.1	16.7
Glaxo	-3.7	12.9	-2.9
Acme	34.5	23.1	25.0
BPI/Rhone Poulenc	7.0	2.3	18.2
EDCL	27.3	-54.4	58.1
Hoechst	-5.3	2.8	18.9
Ciba-Geigy	42.9	20.0	11.1
Organon	43.5	9.1	3.9
ICI	14.1	29.9	32.5
Squibb*	9.1	-12.5	0.0
Average	18.5	8.9	17.7
Average without EDCL		13.8	

**Squibb ceased trading in October 1991*
Source: Drug Administration, 1992

The causes of the difficulties are placed firmly on some production constraints in the Drug Policy and on the price control mechanisms operating in the country.

Production constraints

The NDP has five criteria that deal with the economic and commercial aspects of pharmaceutical manufacture. The first two provide protection against the import of finished drugs or raw materials if sufficient local production is available to meet the country's needs. This is firmly in line with the NDP's objective of encouraging local production of drugs, particularly essential drugs. It also makes economic sense for the country as a whole by helping to keep import costs and therefore loss of foreign exchange to the lowest possible level. The only proviso is that this concept is viable only if the quality of the locally produced products and raw material can be assured. Quality is such an overriding concern, that it is covered in Box 9 beginning on page 55.

The final three economic criteria prevent multinational companies from manufacturing antacids and vitamins, eliminate licensing agreements if the same or similar product is available or manufactured in the country, and prevent companies that do not have a factory in the country leasing spare capacity in another company's factory to manufacture drugs.

Such measures were seen as absolutely vital in 1982 as a means to stimulate local production. In today's more militant 'free market' environment, proponents of business see these criteria as discriminatory and unnecessary. However, Bangladesh is one of the world's least developed countries (LDCs). As such, it has barely benefitted from the supposed advantages of the 'free market' system, nor is it likely to do so in the immediate future, given the low level of industrial infrastructure in the country. There is international consensus that LDCs like Bangladesh need to be given special consideration to develop their technological, commercial and economic base, and that criteria such as these are one way of trying to do that. Here again, the two sets of arguments derive from different contexts. Each is valid within its own context, but when they confront each other, conflict emerges and some hard choices have to be made.

There are three fast-moving high-volume therapeutic sectors: antibiotics, which account for about 29% of sales; and vitamins and antacids, each of which produces about 8% of total sales in the country. Most of the major companies are competing in the antibiotic sector, but the multinationals want a piece of the vitamin and antacid trade. Local companies do not see this as a major threat. On the other hand, allowing the multinationals to produce vitamins and antacids does little to improve the technological base in the

country: local companies already possess the technology and the expertise to produce these drugs. If there is a decision to let the multinationals produce these simple products, it may be wise for the government to preserve the right to set production quotas on particular essential drugs to ensure that the market does not become inundated with only the fastest selling items.

The licensing question is also complex. Two factors are at work here: cost and quality. One argument is that this type of licensing agreement is really a way in which a multinational company can charge high prices or royalties for the right for another company to manufacture its product locally. This is seen as exploitative and a one-way flow of resources out of the country, something that should be stopped. The other argument is that a licensing agreement is actually a two-way flow. What comes into the country is technical expertise, know-how and support services to help improve Good Manufacturing Practice and to ensure quality control of the highest standard. Also, this may be a way of helping the local industry to continue to upgrade its production processes and get access to and make use of the latest technologies.

Similarly, the question of whether a multinational company should be allowed to lease production capacity from another company has overtones of exploitation and quality questions.

The solution to these issues may lie in allowing such arrangements, subject to guarantees of inputs to improve the training of staff in local factories, to upgrade quality control practices, and perhaps to assist in the installation of new equipment. There should also be the idea that licensing and other agreements are not meant to lead to monopoly situations or to prevent local production. Rather they should help pursue more flexible ways of stimulating the continued improvement of and investment in the local pharmaceutical industry.

Price control

Although holding down prices has been a major achievement of the NDP and the Drugs (Control) Ordinance, the pharmaceutical industry finds these controls excessive and is demanding their removal, despite having been represented on the committee that drew up the price controls. The industry says:[23]

> All price controls on drugs and medicines should be immediately withdrawn. Doctors and market competition are better means of control.... All controls in the import of raw materials should be withdrawn.

The current pricing policy and procedures were adopted in 1988 on the basis

of recommendations from a committee that examined possible mechanisms. The committee was chaired by Prof. A. Mannan, Vice-Chancellor of Dhaka University, and included the former Director of the Drug Administration, Dr. Humayun Hye; the Managing Director of Beximco, Salman Rahman, who is now President of BASS; and Dr. Zafrullah Chowdhury, Chairman of the Gonoshasthaya Kendra Trust, a health and community development NGO that also owns a pharmaceutical factory that produces essential drugs.

The mechanism that was finally arrived at involves classifying the drugs into five categories, according to the degree of difficulty in manufacture and the level of quality control required. These are:

- drugs that are only repacked and have no formulation processing;
- oral liquids, creams, ointments, powders, emulsions, tablets, capsules, dry syrups and suspensions, other than antibiotics;
- oral antibiotics, coated tablets, sustained release dosage forms, soluble tablets, suppositories and vaginal tablets;
- hormonal preparations, some sterile preparations and those which may require special conditions or facilities for manufacture; and
- products that require complete aseptic facilities or are of a highly specialised nature.

Taking the cost of raw materials and packaging as the base, fixed percentage markups are then applied according to the type of drug. Production, overhead cost and profit is permitted within a range of 17 to 54% according to the complexity of the manufacturing process. Adding on the trade commission, and the retailers' commission means that the final maximum retail price (MRP) is permitted to be marked up above the raw material and packaging costs at percentages ranging from 50 to 225%. When the price of one manufacturer's drug has been fixed, it also applies to similar products of other manufacturers – a similar product being one that contains the same active ingredient(s) in the same quantity and in the same dosage form.

One industry spokesperson said, 'It is hard to come up with a rational pricing policy. This one is particularly bad. The policy permits prices that we cannot sell some products at and other prices where losses are being made. The same price for all companies also makes no sense.'

Despite the tough demand by the FICCI that price controls at the import level be withdrawn, most company officials (both multinational and national) admit that they can live with import price control. And, given the probable

In theory, drug companies and governments should work in partnership to raise health standards: the companies by creating revolutionary new treatments, governments by deftly allocating tax revenues so that their health services can afford them. In practice, that relationship is rapidly going wrong, because of the astronomical prices drug firms are charging for their innovations.

– *The Economist*, 'The cost of drugs: hard to swallow', 18 April 1992

correlation noted in the previous chapter between the imported raw material price and the retail price, it would be unwise to relax the import controls. In any event, it would be difficult to go back to the uncontrolled days of the 1960s and 1970s. Now, WHO provides an international list of a range of raw material prices from reputable suppliers that is an adequate guide to fair prices. In one or two exceptional cases, it may be necessary to purchase at a higher price in order to be absolutely certain of getting a particular quality of raw material, or a material that is only available from one source. However, those should be seen as exceptions; for almost all drug production within Bangladesh, raw materials that meet the standards set by the British or US pharmacopoeias will provide adequate assurances of quality.

At the retail level, however, there may be a case for relaxing the control significantly. At the moment, the price control mechanism meets one of the objectives of the NDP – making drugs more accessible because of low prices. It does not, however, provide any real incentive or reward for quality.

This has ramifications for the future health of the industry and for its overall structure, not to mention the health of the people of Bangladesh. The answer, however, is not likely to be found in the simple prescription offered by the industry of no control whatsoever. Relying on market forces and wise economic prescribing of doctors to keep retail prices stable is unlikely to work. Experience from the Philippines, where a national drug policy failed to consider pricing questions, shows that drug prices have doubled since its policy began to be introduced in 1987.[24] Equally, the public sector/private sector argument does not work for prices any more than it does for drug selection. Industry representatives have suggested controlling the prices in the government sector (which are, in any case, below the MRP because most of the supply comes from EDCL) and letting the private sector float free. The logic is that the poor will get their medicines from the public sector, while those who are better off will not mind paying a little more for their drugs. The reality is that the poor, too, are forced to purchase on the private market.

Some price control is needed. Even in industrialised countries, governments are looking at ways to curb high drug prices, as Box 8 on page 51 describes. In Bangladesh, the best pricing system would be one that encourages and rewards the production, prescription, dispensing and use of quality products. One suggestion is to allow the quality control expenses to be included as part of the starting cost, so the base price would be made up of raw materials, essential packaging and quality control costs. Another approach is to allow an extra percentage on the MRP for companies that can prove they have invested in quality control. Both ideas carry a potential problem: quality becomes equated with higher prices, which is not always the case. Some

8. Price control in industrialised countries

In most industrialised countries the increase in the drugs bill has outstripped growth in retail prices for nearly a decade. As a result, many governments have introduced or strengthened controls on drug prices. For many years the French government has controlled the country's drug prices, which are among the lowest in the world. It has recently introduced a plan to further cut the cost of medicines to the health care system by requiring firms to estimate likely annual sales of new drugs. If the figure is exceeded, the company has to either refund the difference or cut the price of the drug. In Germany, companies used to be free to price drugs as they wished; however, in 1988, the German government introduced several measures to reduce the health bill services, most of them involving the patients paying more for drugs. In the USA, a system of a pricing review board – similar to that operating in Canada – is under discussion. If adopted, this would require companies to justify their pricing by taking into account changes in the consumer price index, the costs of other products in the same therapeutic category and the cost of the drug in other countries.

Source: 'The cost of drugs: hard to swallow', *The Economist*, 18 April 1992, p. 72

low-priced drugs in the country are of excellent quality. Another idea is to examine the cost structure of the different companies producing the same product lines and calculate the average cost of manufacture of a particular drug. This could serve as the basis for the price calculations. By allowing a small range of prices both above and below the average, it may be possible to encourage some price competition.

One NGO spokesperson thinks that these types of provisions could be introduced in the pricing policy and then should be announced to the public, with an emphasis not so much on the quality, but on the commitment of companies to improve the standards of the industry. 'You can say that they are higher priced because these companies have spent money improving their production or investing in the future of the industry. As long as there is an honest feeling about these things, they will work.'

The Director of the Grameen Bank, Dr. Muhammad Yunus, expressed similar views. 'A basic principle is that of fair business practice. Anyone who is fooling people has to stop. That applies to drug prices as well. For example, excessive packaging is not on. The costs all have to be explained. This is not really a question of control. Control is the wrong word. You need to have a transparent situation, so that you know right from the start what the situation is, what's permitted. In this way, you can prevent over-pricing. The investment that companies make in marketing helps to create a situation where

DR-415
2559

people will do anything to buy the medicine. Business takes advantage of this situation. We have to say, no, you can't do that, you can't take advantage of the poor. If you set the objectives clearly, then the rest is taken care of.'

If the pharmaceutical industry is saying it is being squeezed because we are not letting them make all those useless products, well, fine, it's true. They are being squeezed. But the squeeze is not on making essential drugs. They can make as much of the essential drugs as they like.

– Brigadier Dr. Mukhlesur Rahman Khan, Director, Bangladesh Drug Administration, July 1992

Balancing industry and health

Setting the objectives is what the entire debate around the Drug Policy is centred on. It is an attempt to balance conflicting demands.

A slogan above the door of the director of the Institute of Public Health and Nutrition in Dhaka reads: 'Deserve, then demand'. In many ways, it could be a credo for dealing with the demands of the pharmaceutical industry in Bangladesh. The pharmaceutical industry is running on a tight margin with very little room for manoeuvre. However, so too is Bangladesh. Why, then, should industry receive special treatment?

Because, says Salman Rahman, President of BASS, the pharmaceutical industry can be a powerful engine for industrialisation and development, particularly if it expands into exports. 'Fantastic export potentials for our pharmaceutical products now exist.'[25] Here again is a business argument: expansion is necessary, methods to increase sales are important. A strong and vibrant pharmaceutical industry, even one with export potential, will be beneficial to the country, but does it improve health?

The policy issues regarding pharmaceuticals have been largely decided upon within Bangladesh over the past 10 years. The supply of medicines and assuring their quality is being worked on – too slowly for some, perhaps. But the principal question that still remains, the one that probably has the most bearing on health, relates to the rational use of medicines. What is happening in the health care system to the drugs that are being produced?

A study carried out at Jahangirnagar University's Department of Pharmacy analysed 49 brands of paracetamol and 31 brands of three different antibiotics – ampicillin capsules, cotrimoxazole tablets and cotrimoxazole suspension. In total, the study found 22 of the products (27.5%) to be substandard (see Table 9), usually because of an incorrect quantity of active material.[26] The only positive note about this study was that the substandard drugs, although a large percentage of the products tested, were all produced by small local companies. The total market share of these companies is negligible.

According to the Drug Administration, there are 200 companies with a licence to manufacture allopathic drugs – an increase of some 20% over the 1982 figure of 166 licensed producers.[27] However, only about 110 of them are actually engaged in production and have responded to a recent request from

Table 9: Analytical results of an independent study of drug quality

Product	No. of brands tested	Substandard	
		No.	%
Paracetamol tab.	49	14	28.5
Ampicillin cap.	10	3	30.0
Cotrimoxazole tab.	13	3	23.1
Cotrimoxazole susp.	8	2	25.0

Source: *Roy, J. (1992).* Current status of the quality of the marketed drugs in Bangladesh *(mimeo). Savar: Jahangirnagar University, p.7*

the Drug Administration to submit production statements. Of these 110 companies, the top five control 50% of the market, the top 10 control 75% of the market and the top 20 control over 90%. About 30 companies are considered to be the major production units.[28] The remaining 80 companies actually engaged in production are unlikely to ever make any significant impact on the country's pharmaceutical market. If these small companies that are the primary source of substandard products were to close down, there would be no problem regarding availability of essential drugs.[29]

However, the existence of even one company regularly producing substandard drugs – no matter how small a share of the market it may have – is enough to undermine confidence in the quality of all the locally produced drugs. No matter what people's views are about the NDP, there is unanimity within the country that improving the quality of medicines is important.

Anwarul Islam Bobby, editor of the *Morning Sun* and *The Pulse*, is a vehement opponent of the NDP, but he is equally strong about the need to take steps to improve quality control. 'Nothing has been done about quality control. With such a strong Drug Policy, how can these plants exist that are making substandard products? These small companies, about 170 of them are just slums. You can't make good quality medicine there. There needs to be a crackdown on the small side of the market.'

Ultimately, quality control is up to the manufacturers, with the Drug Administration and the DTL acting as the watchdogs. However, both are understaffed, undertrained and underequipped to perform that function properly. Nor is this a new phenomenon. A 1989 report[30] confirmed the problem, and a series of consultants over the years have also signalled the need to strengthen these facilities.

The Drug Administration has a total staff of 120, 90 of whom are working in the Dhaka office. The remaining 30 are inspectors who are posted around the country, including Dhaka. Their task is to collect samples of medicines from different locations, monitor the performance of dispensers, and visit factories to check on Good Manufacturing Practice. Brigadier Dr. Mukhlesur Rahman Khan, Director of the Drug Administration, says 'I often just drop in on some of these factories unannounced, just to see what is really going on. When we have an inspection, everything looks fine because they know in advance when we are coming. So I drop in, not to check on them, but to help them, to point out what they need to improve if they want to continue to produce drugs. This is a life and death matter. If they want to continue to produce drugs, they have to do it right. If they can't do it right, or don't want to, they should switch to some other type of production.'

At the two quality control laboratories, there are simply not enough staff, nor is there enough of the right equipment to process even the samples collected by the Drug Administration's inspectors. Even the most conservative estimates suggest that the number of samples tested needs to increase by at least three times, and ideally by about six times the current volume. But as well, there needs to be a better system of carrying out the tests. Just as the factories seem fine when an inspection occurs, there are strong suspicions that the quality of the samples being tested is remarkably high.

Dr Majed of the BMA is one of several people who have looked at the quality control problem in the country and concluded that a more systematic programme of testing is required. 'There is a proposal about how to deal with substandard drugs that is now lying with the Law Ministry awaiting its approval,' he says. 'First, the Drug Testing Laboratory facilities need to be increased. Then the DTL should collect the drugs and register them according to a code number, so that no one knows which drug belongs to which company. Then they are tested, and the results checked against a set of penalties. The penalties are automatic and they vary in severity according to the type of substandard practice. If it is only a small degree of substandard, then the penalty is small. But if it is substandard by say 90%, then I think the manufacturer should be hanged. Quality control cannot be compromised upon, never, never, never.'

Another problem that has been occurring recently was discovered by one of the multinational companies. Five consignments of antibiotic raw materials were found to be substandard. Some of the antibiotic intermediate was taken out and replaced with starch and other substances that made it look almost perfect, then the container was re-sealed. In one case, the contents of a complete drum were replaced. The company suspects that this is happening

9. Quality control of drugs

The President of the Bangladesh Medical Association (BMA), Dr M.A. Majed, and the Vice-President of the Bangladesh Pharmacy Council (BPC) and former President of the Bangladesh Aushad Shilpa Samity (BASS), are both convinced that the quality of drugs has deteriorated since the Drug Policy was introduced. They go so far as to say that before the Drug Policy, there were no substandard drugs in the country. The Foreign Investors Chamber of Commerce and Industry (FICCI) says that 'spurious drugs manufactured from substandard raw materials have flooded the country'.[31]

The national Drug Testing Laboratory (DTL) has test results that tell a different story. As Table 10 indicates, the drug samples tested over the years show an improvement in quality. The number of substandard products that have been withdrawn over the years is quite low. One study found that between January 1988 and July 1991 there were withdrawal notices in national newspapers (a requirement for drugs found to be substandard) for 143 items.[32] The State Minister for Health, Sirajul Huq, told the Bangladesh parliament that between January 1991 and May 1992, a total of 103 medicines had been declared substandard by the government.[33]

Table 10: Drug samples tested by the DTL (1981-1991)

Year	No. of Samples Tested	Substandard Drugs No.	%
1981	327	118	36
1985	1187	169	15
1989	2367	238	10
1990	3555	298	8
1991	2331	219	9

Source: Drug Administration, 1992

in the port at Chittagong. The company's own quality control testing found this, but some of the smaller manufacturers would not test their raw materials as thoroughly. The Drug Administration was notified about the problem, but the company said it was not aware of any action being taken. A spokesperson for the company commented, 'the Drug Administration does not have enough staff and quality is not a priority for them.'

Plans to strengthen the drug testing facilities and improve the work of the Drug Administration are included in the World Bank's five-year programme.

WHO will be playing a major role in helping to provide much of the technical expertise for this.

Another suggestion that has been made is that the international agencies like WHO and UNICEF could organise a Good Manufacturing Practice survey among some of the companies with an independent team. This would also be a learning experience for the companies. If the results were communicated to the public, to say these are the good companies, these are the ones that make good drugs, the impact would be that people would develop confidence in Bangladeshi drugs. Companies that are found lacking in quality practices could be given a short time period and perhaps some technical help to get their production up to standard. If this is not done in the established time period, the license to produce medicines should be revoked.

Encouraging quality control is also possible by relaxing the import duty on quality control equipment. Although the duty on production equipment is only some 10%, duty on quality control equipment ranges from 20-100%. This is not an incentive to invest in quality control.

References:

1. Laurence, R. (1989). 'Bangladesh: faith in the future', *Health Horizons*, No. 6, January, pp. 24-5
2. Jayasuriya, D.C. (1985). *The Public Health and Economic Dimensions of the New Drug Policy of Bangladesh*. Washington: PMA
3. BASS (1986). Open letter to Members of the Parliament of Bangladesh, 9 November
4. Kabir, S.H. (1992). Letter from the Foreign Investors Chamber of Commerce and Industry to Chowdhury Kamal Ibne Yusuf, Minister of Health and Family Welfare, 3 May
5. Islam Bobby, A. (1991). 'Bangladesh's blunder: the Drug Policy', *The Morning Sun*, 11 December, pp. 1 & 3
6. Kabir (1992). op cit
7. There were actually 11 multinational companies with production facilities in Bangladesh: Ciba-Geigy, Fisons, Glaxo, Hoechst, ICI, Organon, Pfizer, Reckitt & Colman, Rhone- Poulenc/BPI, Squibb, and SKF. In addition, several multinational companies operate in Bangladesh without a factory, but with an import office. These include: Roche, E. Merck, Wyeth/Ayerst, Medimpex, Sandoz and Bayer. Both Medimpex and Bayer, however, have links to local companies. Medimpex is a part-owner of Ambee Pharmaceuticals and Bayer has an open-ended licence agreement with Beximco. The NDP called for the ending of licence agreements once they reached their expiry date; however, this one had no date of expiry, so it remains in effect. The arrangement between Medimpex and Ambee is permitted because the law considers that owning even as little as 5% of a company constitutes part- ownership, so it is not a third party licence. Ambee is simply making products for one of the owners.
8. Anon. (1992). 'Bangladesh sale is welcomed as "positive move"', *Pharma World*, No. 9, p. 9
9. Anon. (1992). 'ICI PLC's shar es sold to local management', *The Daily Star*, (26 Feb)
10. Anwar, S. (1992). 'Pharmaceuticals looking abroad', *Dhaka Courier*, 3-16 April, p. 21
11. Anon. (1992). 'Sale of heroin and phensedyl on increase at Jessore', *The Pulse*, 13-26 May
12. Kabir (1992). op cit
13. WHO (1988). *Guidelines for Developing National Drug Policies*. Geneva: WHO, p. 10
14. Rucker, T.D. and Schiff, G. (1990). 'Drug formularies: myths- in-formulation', *Medical Care*, Vol. 28, No. 10 (October), pp. 928-42

15. Ledogar, R.J. (1975). *Hungry for Profits*. New York: IDOC, p. 25

16. He made a similar statement in an article in *The Pulse*: Anon. (1992). 'Drug Ordinance was a deterrent to healthy growth of industry', *The Pulse*, 24 June to 7 July, p. 1

17. Kanji, N. (1992). 'Action at country level: the international and national influences' in *Drugs Policy in Developing Countries* (Kanji, N., Hardon, A., et al) London: Zed Books, p. 89

18. WHO (1991). 'An interview with Nigeria's Minister of Health', *Essential Drugs Monitor*, No. 12, pp. 4-5

19. Kabir (1992). op cit

20. WHO (1988). op cit. p. 31

21. Melrose, D. (1982). *Bitter Pills*. Oxford: Oxfam, p. 37

22. World Bank (1990). *World Development Report 1990*. Oxford: Oxford University Press, p. 180

23. Kabir (1992). op cit

24. Discussion at a seminar on: The Role of National Drug Policies in Social Transformation: a challenge for the Media, 21- 23 February 1992, Manila, the Philippines

25. Anwar (1992). op cit

26. Roy (1992). op cit. p. 7

27. Melrose (1982). op cit. p. 37

28. Rahman Khan, M. (1992). *Drug Situation in Bangladesh* (mimeo). Dhaka: Drug Administration, Ministry of Health and Family Welfare, p. 5

29. Roy (1992). op cit. p. 11

30. Islam, K., Martinussen, J. and Rifkin, S. (1989). 'Bangladesh Country Case Study' in *An Evaluation of WHO's Action Programme on Essential Drugs – Volume 2: Country Studies*. London & Amsterdam: London School of Hygiene and Tropical Medicine and Royal Tropical Institute

31. Kabir (1992). op cit

32. Roy, J. (1992). *Current status of the quality of the marketed drugs in Bangladesh* (mimeo). Savar: Jahangirnagar University, p. 1

33. Anon. (1992). '2,500 doctors unemployed', *Bangladesh Times*, 7 July

CHAPTER 3

Towards the Future

THE MANAGING DIRECTOR of the pharmaceutical company paused for a moment while he was talking about the rational use of drugs. Then he leaned forward across his desk, his eyes having taken on a new intensity, and began to describe a scene that he had witnessed.

'I remember once being outside a clinic and I saw an old woman with one vial, just one, of penicillin that she needed. She didn't even have the money to afford the sterile water for the injection. But she had gone to the dispenser beside the clinic and said that the doctor had told her that the dispenser would help her with the injection. For as long as I live, I will never forget the image of that old woman.'

'How to get health care to the people is the question,' said the managing director, as he sat back thoughtfully.

A people's health care system?

It is a question that has been giving Bangladesh's Minister of Health and Family Welfare 'nightmares'. He confessed to a gathering of the Bangladesh Pharmaceutical Society in July 1992 that he was not certain about whether the country's complex health care system was actually reaching the people. 'Are the medicines and the money and the facilities really reaching the outlying areas? There are supposed to be nine doctors in each facility in the rural areas, but I do not know whether they are there.'

He is right to be concerned. Estimates suggest that no more than 35% of the population have access to government health services,[1] although a UNICEF report puts the figure at 45%.[2] Estimates also suggest that almost 40% of the population do not get free medicines to which they are theoretically entitled,

The rational use of drugs demands not only that the right drug be prescribed for the right indication, but that it be readily available when needed, at a cost that people can afford, that it be taken in the right doses, right route of administration, right intervals of time and right duration.... It is therefore, certain that the rational use of drugs concerns "all the concerned people" namely the manufacturer, the prescriber and the consumer.

– Prof. Shah Abdur Rahman Chowdhury, a pharmacologist at the Institute of Post Graduate Medicine and Research (IPGMR) in Dhaka, 1991

but must buy them.[3] Patients pointed out that the allotted quota of medicine was not being distributed properly, and that this problem was 'further aggravated by pilferage of essential drugs' from the health centres.[4]

Two broad strains can be discerned in health policy since the formation of Bangladesh in 1971. The first is the explicit espousal of population control as the major priority in development planning. The second is the continuing emphasis on professionalisation and curative in-patient services at all levels of the health care system.

– M.O. Rahman, researcher, 1990

The Bangladesh health care system is renowned for its two 'wings': health and family planning. For years these two wings have been integrated only at the top level of the ministry. The system is supposed to function as follows. At village level there is one pair of health and family planning workers, a (male) health assistant (HA) and a (female) family welfare assistant (FWA) for every 4-5,000 people. The next administrative level, the union, is the location for the first health facility – the health and family welfare centre (UHFWC) – that is meant to provide outpatient care to a population base of about 20,000. The facility has five staff: three assistant health inspectors (AHI), one family planning assistant (FPA) and one family welfare visitor (FWV). Above this is the sub-district or upazila/thana, where a health complex with 31 beds and outpatient facilities is supposed to be staffed by 60 personnel, including eight graduate doctors, one dental surgeon, five staff nurses and two laboratory technicians. Each district has a hospital with various specialists available.[5]

The key delivery channel for primary health care is supposed to be the upazila health complex (UHC), which acts as a nucleus for the union centres and staff. However, much of the actual delivery of PHC rests on the shoulders of the HAs and FWAs at the village level. Each UHFWC has an annual budget of about 30-40,000 Taka plus three or four drug and dietary supplement (DDS) kits provided by UNICEF.[6]

Upazila health and family planning officers reported during an evaluation of primary health care carried out in 1984 in 24 villages in 12 upazilas that the total medicines received were 'far below the total requirements' and that the most frequently used medicines were often in very short supply.[7] This 'acute shortage of medicines' was seen as 'a serious impairment to the provision of minimum treatment to the patients'.

The evaluation also found that three major reasons accounted for two-thirds of people not visiting the government health centres. These were:

- inadequate attention given by the physician (including lack of careful examination and failure of doctors to listen to the patients, 28.1%);
- medicines are not available (25.7%); and
- government health centres ask for money (12.7%).

Transpórtation difficulties and living a long distance from the centre, long waiting time, poor treatment and infrequent availability of doctors were the other major reasons given.

A study conducted in mid-1988 in one upazila found 'a dismal picture'. Health and family planning staff spent less than half their scheduled working time on the job. Many assigned duties were not done, or done only partially. Suspicion and mistrust best characterised the interactions between the workers of the health and the family planning wings. A shortage of medicines was also noticed. The study concluded that there was 'a tremendous waste of resources' occurring and if they could be more optimally used, better health care might become a reality rather than a policy.[8]

The authors of the study were particularly frustrated by the pattern of delivery of health education that they found. They said that what little health education the HAs delivered was 'very superficial' and 'haphazard'. 'They never tried to make mothers participate, it was one-way communication. HAs did not seem to care whether mothers learned. In turn, the mothers were not interested in what the HAs were saying.'

The study concluded that most rural people are still not aware of the government health services and therefore, 'people's participation in their own health management is still a remote possibility. Health education and motivation, the vehicles for bringing people's participation in health management, is simply rhetoric of the government's health policy; no trace of it was found in the field.'

A recent evaluation of Bangladesh's Health for All (HFA) strategy confirmed the flaws in the system.[9] It noted the absence of a national health policy and therefore the ad hoc nature of communicating policy issues throughout the system. As a result, it found 'inadequate understanding of the primary health care approach and the national HFA strategy'. It also pointed out the poor accountability of staff performance, lack of motivation of health workers and inadequate social accountability. It described community involvement in health development efforts as 'inadequate' and said that health care at the upazila level was 'still oriented towards curative care; preventive and promotive measures have yet to be emphasised in programme activities'.

This national evaluation confirmed the findings of an earlier evaluation of a GOB/DANIDA/SIDA/WHO Essential Drugs Project which concluded that primary health care in Bangladesh 'has taken the form of curative care provided through the rural level health centres'. Although immunization, some health education and public health measures are attempted, the evalua-

In both the industrialised and the developing world, the actual use of medication often bears strikingly little resemblance to principles of scientific therapy based on sound experimental or clinical data. The costs of such non-rational drug use are enormous in terms of both scarce resources as well as adverse clinical consequences of therapies which may have real risks but no objective benefits.

– Management Sciences for Health (1992). *A Report on the Promoting Rational Drug Use Training Course, Kathmandu, Nepal, 1-13 March 1992.* Boston: MSH

tion said 'there is almost no scope of the community to get involved in the delivery of health care' nor is it encouraged to take the initiative for the self-promotion of health. The evaluation concluded that the government health service 'does not at all interact with the community. Therefore, the relationship of the people with the health centre is only that of the receivers of curative services. The health care structures are virtually alienated from the people.'[10]

The efforts made by some NGOs stand in sharp contrast. One researcher points out that NGOs 'are frequently in the forefront of innovations in community health delivery and, as is shown by the experience of Gonoshasthaya Kendra, BRAC and others, are relatively quickly able to implement research findings into actual practice.'[11] BRAC's experience in devising a national programme to teach village women about oral rehydration therapy is explained in Box 10 below.

10. Encouraging community participation

In 1979, the Bangladesh Rural Advancement Committee (BRAC) began a programme to teach oral rehydration therapy (ORT) to 30,000 families in one part of the country. Based on the understanding that oral rehydration was successful in the treatment of dehydration caused by diarrhoea, BRAC's research demonstrated that a homemade solution of a pinch of salt and a handful of unrefined sugar mixed with half a litre of water achieved a comparable effect as the scientific ORS preparation. BRAC realised that it was possible to teach village women how to make this homemade solution and, at the same time, teach them a short seven-point message about diarrhoea prevention and treatment. By early 1980, the Oral Therapy Extension Programme (OTEP) was expanded into a nationwide effort to teach ORT to every village household in the country. Ten years later, BRAC completed the teaching of about 12 million rural households in the country. The programme is considered to be both a quantitative and qualitative success and ORT is now an accepted part of the treatment of diarrhoea throughout the country. BRAC's success was achieved by a persistent emphasis on participation at the grassroots level. Teams of trained female workers went from house to house, from village to village. The teaching method was based on an appropriate use of the local systems and the face to face village meetings, supplemented with meetings in mosques and other village locations. Support for these concepts was also reinforced by national media advertising on radio, television and billboards as well as through folk traditions.[12] Another factor in the success was the consistent research and evaluation effort that was fed back into the programme to ensure that adaptations were made that accurately reflected local needs, attitudes and beliefs, and that enabled an accountability process to be built in that ensured that educational messages were communicated in ways that had a better likelihood of being retained in the communities.[13]

Rational prescribing?

If the health care system is not working well, what hope is there that the use of drugs will be appropriate and rational?

Dr. A.M.M. Khan, Vice-President of the Bangladesh Pharmacy Council (BPC), has no doubts. He told a meeting of the Bangladesh Pharmaceutical Society in July 1992 that 'the rational use of drugs is absent at all levels of the health care system in Bangladesh'.

The whole concept of the rational use of drugs is a relatively new one. It began to emerge in the mid-1980s when WHO realised that the simple availability of drugs does not always solve the problem of drugs use.[14]

An evaluation of the WHO global Action Programme on Essential Drugs found that, in the 13 countries studied (including Bangladesh) that had an Essential Drugs Programme in operation, although the supply and availability of essential drugs had improved, there were still problems in the prescribing of drugs at all levels of the health care system. Excessive use of antibiotics was one of the problems identified.[15] (See Box 11 on next page for more information about the problems of antibiotic prescribing in Bangladesh.)

A major constraint on achieving rational use of drugs lies in the limited time that prescribers spend with patients. A 1988 study described the interaction between the doctor and a patient as 'a meaningless ritual: a shamanistic encounter to inaugurate the distribution of drugs.' Patients spent an average of only one to two minutes with the doctor, during which time a diagnosis was made on the basis of the patient's description of the problem, and the prescription was written. The medicines prescribed often depended on what supplies were available at the health centre that day, not necessarily on what the patient needed.[16]

The evaluation of primary health care carried out in 1984 found that, although most of the sickness reported required physical examination and pathological tests in order to determine proper treatment, 49% of patients were simply given a prescription without any examination.[17]

In 1992, Dr. Zahed Md. Masud, Medical Research Director of the Bangladeshi NGO, UBINIG, carried out a small study of eight prescriber/patient interactions in a general practitioner's chamber in Dhaka. He said that the doctor spent an average of nine minutes with each patient, although half that time was spent in discussions with other people while the patient waited for treatment and advice. Physical examinations took an average of under 10 seconds. There was very little explanation to the patients about the illness or about the medicines

The health delivery system has been reduced into a drug delivery system.

– Farhad Mazhar and Farida Akhter, researchers with the Bangladeshi NGO, UBINIG, 1988

11. Using antibiotics wisely

Antibiotics are powerful and effective drugs that have saved millions of lives since their first use nearly half a century ago as the main agents against infectious diseases caused by bacteria. Yet today, more and more people are dying from infectious diseases that were curable, but for which there is no longer an effective treatment. The reason is that the bacteria have developed resistance to the antibiotics.

'Increasing antibiotic resistance is a result of misuse of antibiotics', says M.K. Choudhury, President of the Bangladesh Pharmaceutical Society (BPS). 'Antibiotic use in this country is increasing. That's not necessarily a good thing. We need to deal with the poor hygiene and sanitation.'

A study carried out in 1980 in one area of Bangladesh found that antibiotics were 'rarely appropriately prescribed' and 'often inappropriately dispensed'. Nearly half of the antibiotics purchased for adults were in quantities that represented less than a single day's dose and it was rare for a full course of therapy to ever be purchased at one time. They were also often prescribed for illnesses for which they were not indicated. One of the reasons for this was identified as being the heavy promotion of antibiotics – all of which were imported at the time – by the large multinationals.[18]

A study in 1984 carried out in two teaching hospitals in Dhaka found that 90% of all antibiotics prescribed over a four-week period were given without any tests to confirm the cause of the infection. In at least one-quarter of cases, the antibiotics were used inappropriately in respect of either disease or duration. A little more than half the patients received antibiotic combinations. Some of the combinations were irrational or harmful; for example, in the medical unit, 10 of the 13 combinations used were irrational or harmful.[19]

A study of hospital and private practitioners treating children with diarrhoea in 1990 found that nearly two-thirds used antibiotics.[20] A survey of public health facilities in 1990 found that antibiotics were prescribed unnecessarily in 23% of watery diarrhoea cases, and only 46% of patients with dysentery received an appropriate antibiotic.[21] Studies carried out in 1991 found rural pharmacies recommending antibiotics for childhood diarrhoea between 76 to 96% of the time, while 78% of rural practitioners said they used antibiotics in all cases of diarrhoea.[22]

There seems little doubt that there is considerable overuse of antibiotics in Bangladesh. At the same time, there is also underuse. Virtually every health worker or researcher in the health field is able to cite incidents where less than a full course of antibiotics is prescribed, dispensed, purchased or taken by the patient. The reasons have to do with the supply of drugs, the costs of drugs and the belief that once the patient feels a little better, there is no need to keep taking the antibiotic.

A prime piece of advice to follow in a country like Bangladesh is: a broad-spectrum antibiotic should not be used where a narrow spectrum product is found to be effective. 'A cannon should never be used to kill a mouse' is the way a 1988 editorial in the *Bangladesh Journal of Physiology and Pharmacology* put it.[23] The other advice the editorial gives is to make sure that an antibiotic is really needed.

A strategy for combatting the increase of resistance is to maintain a selection of 'reserve' antibiotics – drugs that are only used when the usual antibiotics are no longer effective. As well, a major campaign of information and education – of prescribers, dispensers and the public – is needed to encourage the proper use of antibiotics.

being prescribed – how they worked, potential side effects, how to take them, how long for.

Situations like this led the evaluation of WHO's global Action Programme on Essential Drugs to conclude that 'providing the general public and health workers at all levels of the health care system with continuous training and regular information are preconditions for rational drugs use. It is in this area of work that gaps and weaknesses have been identified in the implementation of Essential Drug Programmes (EDPs) and policies. Without appropriate educational strategies, rational drugs use cannot be expected.'[24]

There are conflicting views in Bangladesh about the quality of education that prescribers receive, especially with regard to the rational use of drugs. Dr. M.A. Majed, President of the Bangladesh Medical Association (BMA), says somewhat predictably that the medical curriculum in Bangladesh is:

> adequate for the rational use of drugs in this country. Every aspect is covered. Some doctors who are trained in this country, who have qualified in this country, have worked in the United Kingdom. So their knowledge is adequate. Drug misuse is not caused by any deficiency in knowledge. Sometimes when it appears that a doctor is prescribing irrationally, the intention is clear: he wants to cover all the possibilities at the time, and he is probably right to do so. For example, if a mother brings her child along and the child is sick, she wants the doctor to do something. So there may be some misuse of drugs, but there are circumstances. It is not the doctor who is prescribing irrationally, it is the patient who wants the treatment.

National Professor Nurul Islam is concerned about the standards of education in the country generally and medical education in particular. 'The standard of medical education has gone so low. Recently, a local NGO interviewed 60 doctors for a post and 80% of them did not know how to take blood pressure!' He made the point that of the eight medical colleges in the country, only three are recognised by the British Medical Council. 'It is our moral obligation and social responsibility to improve the standard of medical education.'[25]

The comprehensive evaluation of the HFA strategy concluded that medical education did not cover the problems that were evident in the community and, as a result, medical graduates posted to rural areas were 'alienated from the society and incapable in many case of coping with the health problems'. It also noted that there was no regular mechanism to organise in-service training. It said that the isolated efforts that occurred were often uncoordinated and without follow-up.[26]

Two studies of doctors' knowledge about the Drug Policy and essential drugs confirm the need to do more. A 1987 survey of 44 doctors in three upazilas found that 91% thought their patients had benefitted as a result of the NDP because they were getting a regular supply of essential drugs at low cost, but only 57% thought that they, as physicians, had benefitted. The survey found that 60% of physicians who had worked for more than 10 years were knowledgeable about some of the content of the NDP, 75% of those who had been working for six to 10 years, and 83% of those with less than five years experience. A further difference that was noted was that 23% of government doctors still wrote prescriptions that contained banned drugs, while nearly 39% of their colleagues in private practice included banned drugs on their prescriptions.[27]

A 1989 study of 67 physicians in 10 different districts found that although 86% of the doctors had heard about essential drugs, 69% were not able to explain what was meant by an essential drug. As far as the situation within Bangladesh, 16% of doctors did not know of the existence of an essential drugs list for the country and 87% could not indicate the number of drugs specified for use by health workers at different levels. The study concluded that the lack of knowledge about the government's national policy on drugs is 'impeding its implementation in the field'.[28]

The researcher who carried out the study recommended that information about the NDP and essential drugs should be 'disseminated properly' to all prescribers, that discussions about essential drugs should be included in the programme of all seminars and workshops held on PHC, and that prescribers should be educated about drugs not only during their medical training, but throughout their professional career.

Such continuing medical education should be independent of the pharmaceutical industry, which is acknowledged to be the primary source of information about drugs in Bangladesh.[29] A senior official at one of the major donor agencies working in the health field suggested that the BMA should play a major role in improving training about the rational use of drugs. 'Because of the marketing and promotion of the industry, doctors are open to persuasion and they play a key role in deciding what drugs are used. The BMA should be encouraged to take a lead in the rational use of drugs.' According to its President, Dr. M.A. Majed, 'The BMA plans to revise its continuing medical education programmes on medicines and other health topics. We plan to have these all year round.'

Some change has occurred in the medical curriculum. More emphasis is placed on community health care that is appropriate to Bangladesh, although

this still needs strengthening. Various courses and training programmes for doctors, nurses and grassroots level health workers have also been introduced by government departments and institutions as well as by NGOs. Most of these training programmes have emphasised motivation and commitment to primary health care.[30]

This is in line with the findings of researcher Dr. S.M. Khalilur Rahman who was looking at the problems of the rational use of drugs and the development of a good health care system. He said in 1989 that 'the most profound change required is that of individual behaviour of the personnel linked with the system'.[31]

Traditional medicine

Another major problem of rational drug use in the country is that 'only a small proportion of the population (13-29%) uses the government health facilities. The vast proportion of the population (35-68%) in the rural areas seek treatment from unqualified allopaths and other practitioners.'[32]

Table 11 shows the health seeking behaviour of people that emerged during a major evaluation of PHC in 1984. More recent findings confirm the pattern.

Much of the use and distribution of drugs in developing countries happens outside the control of government health professionals.... The failure of policy makers at national and international levels to pay attention to private and informal drugs distribution channels is serious, as are the consequences of this neglect.

– Najmi Kanji and Anita Hardon, researchers on drug policies, 1992

Table 11: Type of treatment sought for illnesses

Type of treatment	Percentage
Allopathic (from qualified practitioner)	36.3
Allopathic (from unqualified practitioner)	41.6
Homeopathy	7.2
Traditional healers	10.3
Spiritual	4.6

Source: *Khan, M.R. (1988).* Evaluation of Primary Health Care and Family Planning Facilities and Their Limitations Specially in the Rural Areas of Bangladesh. *Dhaka: Bangladesh Institute of Development Studies. p. 188*

A survey conducted in 1989-90 in three Bangladeshi villages found that, on average, only 14% of people suffering from illness approached allopathic doctors. The survey found that 29% contacted unqualified village doctors, 10% contacted mollahs, 28% contacted quacks, and 19% contacted homeopaths.[33]

Only 15-20% of the population uses allopathic health care supplied by the

public sector. The rest are provided through the private sector which also provides the unani, ayurvedic and homeopathic medicines.[34]

If there has been some measure of control introduced into the allopathic drug market, there has been very little done about the traditional medicines. Although the sales value of traditional medicines is estimated to be quite low – in the region of 600 million Taka[35] – the products are often inexpensively priced and the volume of use is thought to be high. And, as Table 12 indicates, there are more manufacturers of traditional and homeopathic products than allopathic producers, as well as a larger number of products.

Table 12: Number of manufacturing units and registered products

Type	No. of manufacturing units	Registered medical products (formulations)
Allopathic	200	4471
Unani	242	670
Ayurvedic	178	3506
Homeopathic	63	650

Source: Drug Administration, 1992

Quality control of the traditional medicines has been described as varying from 'awful' to 'virtually non-existent'. Because there are poorly defined specifications for the medicines and because there is often no real information about the contents, it is difficult to even check that the product contains what it is supposed to contain, let alone evaluate its safety and efficacy. Some success has been achieved in getting the most harmful of materials, such as heavy metals, out of the medicines, but more could be done.

A common complaint aired by the industry, NGOs, academics and health workers is that imitations of many of the allopathic products that were banned in 1982 have been appearing as traditional medicines. This is particularly true of a variety of tonics that are advertised regularly in daily newspapers as cure-alls for sexual problems, baldness, pimples, and lack of energy. Failure to stem this practice and this trade has made it more difficult to resist the pleading by the allopathic industry to produce some tonics for over- the- counter sale.

However, several suggestions have emerged regarding the traditional system.

The underlying philosophy of traditional medicine is herbs. Although most pharmacists and pharmacologists argue that it is usually better to have a pure extract of the herb – the process that has led to many allopathic medicines – there is also some sympathy within the country for allowing the traditional system to operate as long as the basis for the medicines concentrates on a limited number of herbs. Work is going on in several countries, (including Bangladesh) to test the properties of various herbs and determine their safety and efficacy. By using only those herbs that are found to be safe and effective and by limiting combinations, a limited list of products could be developed in the same way as it has been done for the allopathic medicines.

Similarly, the traditional healers, because they are often the first healers that people turn to when illness occurs, are powerful potential allies in efforts to improve the rational use of drugs. By training them to diagnose and refer, and by helping them to realise the role of medicines – whether allopathic or traditional – in health care, they can become positive forces for change within communities, rather than obstacles to good therapy, which is how they are often viewed.

Dispensers

The other 'frontline' workers in the system of health care are the private dispensers. Unfortunately, they are not usually considered part of the health care system. They are simply retailers selling drugs. Officially in 1992, there were 20,000 licensed retail outlets for drugs. Unofficial estimates suggest that at least that number of unlicensed premises are also selling medicines, not to mention an uncountable number of small shopkeepers and stallholders throughout the country who might happen to have a few medicines available along with their food products or cigarettes.

No medicine is supposed to be dispensed without the supervision of a qualified pharmacist. Drugs such as antibiotics, hormones, narcotics and benzodiazepine tranquillisers are only supposed to be sold on prescription. Walking into a pharmacy in Bangladesh and asking to see the pharmacist is likely to be greeted with disbelief, or perhaps some nervous smiles as the store owner realises that he might be breaking the law. It would also be a rare event to be asked for a prescription for any product.

'We are often asked why a pharmacist is necessary just to sell drugs from a pharmacy,' says Nasser Shahrear Zahedee, General Secretary of the Bangladesh Pharmaceutical Society (BPS). 'Well, you don't need a pharmacist if all you want to do is sell drugs. But if you want to dispense medicines ethically, morally and professionally, then you need to have pharmacists.'

Most of the people running even the licensed shops are untrained. About 12,500 of them have had a short four-month training course that provided them with a certificate. It is a pragmatic way to deal with the burgeoning number of retail outlets for drugs. However, it does not really improve the quality of dispensing or the quality of health care.

A longer term strategy is needed to plan for the situation in the future. There needs to be a decommercialising and a professionalising of the dispensing of drugs. A starting point could be no new issue of licences unless basic ethical standards are complied with and unless adequate training has taken place. Existing licences for pharmacies should be ended when the present owners die. At the same time as there needs to be preparation for reasonably well trained people to operate pharmacies in the future, existing dispensers need to have intensive and regular training courses. Incentives should be given to those who attend courses and put into practice the training.

Drugs are always regarded as a double-edged sword. They can offer a cure when used rationally. On the other hand, they may be dangerous or sometimes may even take a life when used irrationally.

– Prof. Shah Abdur Rahman Chowdhury, a pharmacologist at the Institute of Post Graduate Medicine and Research (IPGMR) in Dhaka, 1991

Planning for the future

The problems that emerge in terms of the NDP, the rational use of drugs, and general improvements in the health care system are broadly similar. They include the absence of a formal national health policy, poor planning, the lack of an effective health manpower development strategy, little accountability, weaknesses in training and education of health workers, little public education on health and rational use of drugs, and inadequate community involvement. The solutions to these problems are not easy, particularly when the country faces similar issues in other sectors such as education.

Two researchers who have examined drug policies in several countries pay particular attention to the need to look at the total environment in which drug production, supply and use is occurring. 'In working at the grassroots level it becomes obvious that the change towards a more rational use of pharmaceuticals will be impossible so long as the environment in which people take drugs remains so irrational.'[36]

In Bangladesh, part of the equation for rational drug use is now in place. The basic selection of essential drugs has been made. Some minor refinements and modifications may be needed to keep that selection up to date, but the drugs that are required to treat the prevalent disease conditions in Bangladesh are on the market. Now, work is needed on the rest of the equation to ensure rational drug use: the right diagnosis, the right dosage, the right duration.

Side by side with that is the need to also develop some quality assurance mechanisms within the health care system as a whole. WHO has been helping the government operate a programme of Intensified Primary Health Care

(IPHC) in 11 upazilas that is planned to spread to nearly 60 upazilas. The programme has already trained 13,000 local volunteers and is targeting another 40,000. The volunteers are given some seed money to get started and they go round the villages training people in antenatal care, growth monitoring, infant health and the importance of immunisation. With a dropout rate of only about 2-3%, the programme is being viewed as one way of encouraging community involvement and of encouraging equity in health care.

Beyond this, there needs to be coherent planning, based on solid research on the factors that influence drug selection and use. The common illnesses prevalent in the country or in a particular location need to be identified. Standard therapeutic guidelines for treating those diseases need to be developed. Then it is necessary to ensure that the appropriate drugs are available in sufficient quantity to meet the needs. Health workers at all levels need to have better education about the rational use of drugs, including putting this in the context of community needs. This will require even more efforts to improve the medical curriculum and to strengthen in-service training for doctors and other health workers. In fact, given the reliance of the health care system on grassroots health workers, improvements in their training and education are more likely to rapidly affect the use of medicines in rural areas. In addition, in order for such improvements to have a positive impact, there needs to be a system to monitor the results of training, to audit prescribing practices and feed that information back into the system, back to the health workers who are writing the prescriptions. And it is not enough to stop there, or to simply focus on the government health system. The public also needs education about when medicines are needed, which ones are effective, and how to take them. Consumer organisations and other NGOs can play a role in this. Training the dispensers to become part of the health care system, not part of the retail trade will also make a difference. And working with traditional healers, building on the strengths of existing community networks, will also encourage appropriate practices.

While these are difficult challenges, the alternative – to simply let the health care system and the use of drugs evolve in an ad hoc manner – is to court chaos and continued inequity. Bangladesh has been a pioneer in focusing attention on the essential drugs concept and on the need to develop a drug policy. It can continue this pioneering work by focusing now on the implementation of the policy, by putting the policy into practice more effectively. By revitalising its medical and pharmacy education and training, by improving education for consumers, by working more closely with communities to develop a health care system that meets the needs of the people, and by strengthening the regulatory and quality control mechanisms, Bangladesh can continue to ensure that its people have access to the right drugs at the right price.

References:

1. Islam, K., Martinussen, J. and Rifkin, S. (1989). 'Bangladesh Country Case Study' in *An Evaluation of WHO's Action Programme on Essential Drugs – Volume 2: Country Studies*. London & Amsterdam: London School of Hygiene and Tropical Medicine and Royal Tropical Institute, p. 5
2. UNICEF (1991). *The State of the World's Children 1992*. Oxford: Oxford University Press
3. Islam, et al. (1989). op cit. p. 5
4. Khan, M.R. (1988). *Evaluation of Primary Health Care and Family Planning Facilities and Their Limitations Specially in the Rural Areas of Bangladesh*. Dhaka: Bangladesh Institute of Development Studies, pp. 66-8
5. Azad Chowdhury, A.K., Choudhury, S.A.R. and Das, A.M. (1990). *Regulatory Approaches to Rational Drug Use* (mimeo). Dhaka, p. 1
6. UNICEF supplies about 7,000 DDS kits a year for the health wing (including about 400 kits that are distributed through NGOs) and about 20,000 kits for the family welfare wing. The health kits contain 14 items; the family welfare kits contain 18 items.
7. Khan (1988). op cit. p. 93
8. Chowdhury, A.M.R., et al. (1990). *A Tale of Two Wings*. Dhaka: BRAC
9. Das, A.M., Bangali, A.M. and Islam, M.S. (eds). (1991). *An Evaluation of the National Health for All Strategy: Bangladesh*. Dhaka: Directorate-General of Health Services, pp. 20 & 37
10. Mazhar, F. and Akhter, F. (1988). *Illness Behaviour: Experiences from Six Villages in Bangladesh. Part A: General Indicators*. Dhaka: Essential Drugs Project, p.16
11. Rahman, M.O. (1990). *Country Report on Bangladesh* (mimeo). Boston: Harvard University, p. 23
12. Hossain, H., Dodge, C.P. and Abed, F.H. (eds). (1992). *From Crisis to Development: Coping with disasters in Bangladesh*. Dhaka: University Press Limited, p. 208
13. Commission on Health Research for Development (1990). *Health Research: Essential link to equity in development*. Oxford: Oxford University Press, p. 15
14. Hardon, A. and Kanji, N. (1992). 'New horizons in the 1990s' in *Drugs Policy in Developing Countries* (Kanji, N., Hardon, A., et al) London: Zed Books, p. 115
15. Kanji, N. and Hardon, A. (1992). 'What has been achieved and where are we now?' in *Drugs Policy in Developing Countries* (Kanji, N., Hardon, A., et al) London: Zed Books, p. 102
16. Mazhar and Akhter (1988). op cit. p. 17
17. Khan (1988). op cit. pp. 66-8

18. Hossain, M.M., Glass, R.I. and Khan, M.R. (1982). 'Antibiotic use in a rural community in Bangladesh', *International Journal of Epidemiology*, Vol. 11, No. 4, pp. 402-5

19. Rashid, H.U., Chowdhury, S.A.R. and Islam, N. (1986). 'Pattern of antibiotic use in two teaching hospitals', *Tropical Doctor*, Vol. 16, (October), pp. 152-4

20. UBINIG (1990). *Use and Abuse of Children's Medicine*. Dhaka: UBINIG

21. UNICEF (1992). *Rational Use of Drugs in the Management of Acute Diarrhoea in Children*. Dhaka: UNICEF, p. 3

22. Ibid. pp. 6 & 9

23. Hussain, A.H.M. (1988). 'Rational prescribing of antimicrobials', *Bangladesh Journal of Physiology and Pharmacology*, Vol. 4, No. 1, (June)

24. Kanji and Hardon (1992). op cit. p. 98

25. Anon. (1992). 'Drug Policy not final one', *The Pulse*, 16 April, pp. 1-2

26. Das, et al. (1991). op cit. p. 42

27. Kader, K.M. (1987). *A Study on the Physician's Perception of the Drug Policy with Special Reference to the 45 Essential Drugs in Three Selected Upazilas* (mimeo). Dhaka: NIPSOM

28. Khalilur Rahman, S.M. (1989). *Perception of Drugs by the Physicians in the Context of Drug Policy in Bangladesh* (mimeo). Dhaka

29. Ibid

30. Das, et al. (1991). op cit. pp. 39-41

31. Rahman, S.M.K. (1989). *Report on the Baseline Data Collected in the Extended Project Area of EDP*. Dhaka: Essential Drugs Project, p 12

32. Azad Chowdhury, et al. (1990). op cit. p. 13

33. Quddus, Md.A. and Ara, S. (1991). *Nutrition in Rural Communities (with seasonal variations)*. Kotbari, Comilla: Bangladesh Academy for Rural Development, pp. 23 & 58

34. Islam, et al. (1989). op cit. p. 5

35. Hye, H.K.M.A. (1992). *Ten Years of the Bangladesh Drug Policy* (mimeo). Dhaka, p. 16

36. Hardon and Kanji (1992). op cit. p. 116

Afterword

SHORTLY AFTER LUNCH, the heavy monsoon rain ended and the sun came out and began rapidly drying the waterlogged landscape. By the time the school children began to walk through the fields on the way to their nearby villages, it was possible to forget that it had been raining so heavily only hours before.

The children walked in small groups, sometimes in pairs or threes, talking as they went, occasionally giggling or laughing. Proudly they carried their notebooks, the symbol of their education. Collectively, they symbolised the future of Bangladesh as they walked home that peaceful afternoon in July 1992.

These were children who had survived, who had made it through the first five years of life. These were children who already had the beginnings of a healthy future. Yet like all children in Bangladesh – whether they are like these who are searching for understanding and knowledge, or the babies carried on the shoulders or hips of their mothers through the Dhaka traffic, searching for enough food for one meal – they already bore a heavy burden.

'Every Bangladeshi child who comes into the world is already carrying a $360 loan on his or her back' as a result of the national foreign debt, says the director of one of the country's health NGOs.

Bangladesh is a country that cannot afford to waste its resources, whether they are natural, financial or human. For many years, Bangladesh has traded on 'the misery of the poor, first to attract sympathy, and then to demand aid'.[1] On the streets of its towns and cities, on the barges on its great rivers, in the fields in the rural areas, one cannot help but be moved by the poverty. At the same time, one cannot help but notice the strength and the determination of

If you are going to do policy, it means among other things, structural changes ... you have to look for people in the government who have graduated beyond the traditional level of administration and the traditional definitions of bureaucracy.... You cannot leave anything to chance particularly when you draft a policy that seeks to change, in a fundamental way, structures, historical practices and the behaviour of people.

– Dr. Alfredo R.A. Bengzon, former Secretary of Health of the Philippines, 1988

its people to survive. To do so, they work hard and long, they use their skills to invent uses for materials that more affluent societies would simply discard.

As well, Bangladesh is a land of poets, a land filled with culture, with a rich artistry among its people. Sadly, the poetry gets lost sometimes in the violence of daily life.

For the old woman who can't afford a full course of antibiotics, there is little poetry. For the patients who get cursory examinations, and prescriptions containing more drugs than they need and far more than they can afford, there is no poetry, no justice. For the patients who have to buy their medicines from the private dispensary because of pilferage in the system, there is no poetry, no justice, no equity.

The National Drug Policy may not be poetry, but it does talk of justice and equity. In developing a National Drug Policy, Bangladesh was rightly praised for its courage and commitment. Over the past 10 years, considerable progress has been made. The production of drugs is reasonably well controlled. The supply of drugs, although patchy in places, is improving. Stopping the leakage in the government system might help to increase accessibility. Proper education about which drugs to use and when and how, might also help. The quality of drugs is becoming more reliable. But more effort needs to go into this, more emphasis on the importance of quality, not just at the production end, but at the dispensing end as well.

The final piece in the pharmaceutical puzzle is perhaps the most complex: rational use. Without rational use, all the other gains become hollow. The rational use of drugs is the key to transforming drugs from simply another commercial product to a tool in the health care process. And the health care process itself is the key to rational use. If there really is **health care**, if there is quality in the interactions within the health system, then the role of medicines approaches its proper place. Without care, handing out drugs becomes the way of dealing with patients.

As well as being praised the NDP has been criticised. And yet, in all the criticism, there is no real substantive point that makes it obvious why the policy should be scrapped. The problems lie more with the lack of effective implementation mechanisms than with the NDP itself. If the list of essential drugs were reviewed every one or two years to keep pace with pharmacological developments, the shouts about not having access to new life-saving drugs would die down. If the various committees that are part of the registration system met regularly and were composed of competent technical people, the shouts about unnecessary delays in registration or getting permission for

imports or prices would begin to fade. If the pleas to strengthen the testing labs and the Drug Administration itself – recommendations that have been around as long as the NDP – were acted upon, the shouts about poor quality might become a thing of the past.

Sometimes in all the shouting, no one listens. Charles Medawar, a researcher on pharmaceuticals for the UK-based group, Social Audit, describes this phenomenon in relation to the pharmaceutical industry.

> The industry is so intent on shouting back in response to criticism, just in order to save face, that it never actually listens and, therefore, never actually understands. And, therefore, the criticism increases.[2]

Health professionals, too, have been guilty of shouting simply to save face, to prevent change that is not directed by them. In response, many of the proponents of the NDP and of better practices in the health care system have had to shout back.

In all cases, the shouting is a reflection of the frustrations of working in Bangladesh where every day can be a struggle to survive. As the comment at the beginning of this chapter from Dr. Bengzon of the Philippines points out, 'you cannot leave anything to chance' when you are trying to change structures, attitudes, behaviours and practices. In many ways, a major criticism of the implementation of the NDP is that too much has been left to chance, that too little effort has gone into putting the policy into practice.

The shouting has had a use, it has had a place – confrontation always has a place. It is a legitimate tool for social change. Consultation and conciliation are also useful tools. These are concepts that speak of negotiation, and of give and take. They mean having to let go of some cherished positions in order to achieve a better future for more of the people.

As a recent book on coping with disasters in Bangladesh said:

> 'poverty pulls down society whereas a partnership with the poor can be a basis for improving productivity. NGOs have undoubtedly evolved more efficient delivery of services, particularly in the social sectors, but their outreach in terms of the whole population, while significant and growing, needs to be further expanded as a complement to government and the private sector. The challenge lies in evolving a system of working together – both government and non-governmental and commercial – towards common, realisable goals which are based on human development and not just a focus on

> infrastructure or large scale industrial projects. Development practice should not be reduced to competition to increase clientele, to obtain more resources or to preserve control. It should be conceptualised not merely as a delivery of services but as a process of empowerment, enabling people to participate in the improvement of their lives, to decide for themselves, to use the democratic space to articulate their own goals and their own needs.... If our priority is poverty, we will need to strengthen popular processes and people's institutions so that they can assert their right to decide.'[3]

The goal of the Drug Policy was to ensure that people got access to affordable, reliable, essential medicines. Its objective was always coming from a people's perspective and from the foundation of primary health care. It was always a focus on health first and business second.

It is understandable that business finds the policy 'hostile', at times offensive, and certainly tough to live with. Shouting about that does not help. Listening might, because in the process, the views of business might also be listened to, might also be considered. There will always be an uneasy tension between the health and business interests and the health concerns will have to remain the most important for some time to come. But business too can benefit from a focus on better health. Business has benefitted from the NDP, as have health workers and the people.

As the children continue on their walk through the fields, to and from school each day, some of them might be thinking about going into the pharmaceutical industry, some might think about becoming doctors, some might want to become politicians to try to develop the policies and the practices that will govern life in the next century.

Perhaps, too, a few will want to study pharmacy like the young pharmacy student at Dhaka University who started his studies in 1986 on a three-year course. Six years later, he is still trying to complete the course. The fault does not lie with him, but with the endless disruptions to the functioning of the University caused by unrest, political agitation, and a general dissatisfaction with the lack of quality of the education. He says he wants to complete his degree, then go abroad to take a doctorate. Will he come back? He smiles enigmatically and moves his head and shoulders in a way which signifies the lack of a final decision on the matter.

Perhaps he will come back, and help to put into practice the policies that have been developed over the past 10 years to encourage better health and a more rational use of drugs.

References:

1. Hossain, H., Dodge, C.P. and Abed, F.H. (eds). (1992). *From Crisis to Development: Coping with disasters in Bangladesh*. Dhaka: University Press Limited, pp. 378-9
2. Chetley, A. (1990). *A Healthy Business? World health and the pharmaceutical industry*. London: Zed Books, p. 141
3. Hossain, et al. (1992). op cit. pp. 378-9

From Policy to Practice

The future of the Bangladesh National Drug Policy

Bangladesh received international acclaim in 1982 when it was the first country to introduce a National Drug Policy based on public health concepts such as primary health care and the need for essential drugs. Ten years later, this report provides an independent assessment of the achievements of the Drug Policy and prospects for future improvements in the supply and use of medicines in Bangladesh.

The report provides evidence for:

- increased local production of essential drugs;
- stable drug prices;
- a greater share of production by national companies;
- less dependence on imported products;
- less waste of resources on non-essential or useless products; and
- an improvement in the quality of drugs.

The report also highlights the need to continue this pioneering work by focusing on putting the policy into practice more effectively. By revitalising its medical and pharmacy education and training, by improving education for consumers, by working more closely with communities to develop a health care system that meets the needs of the people, and by strengthening the regulatory and quality control mechanisms, Bangladesh can ensure that its people have access to the right drugs at the right price – and that they are used widely.

National drug policies and essential drugs programmes are now,
and in the foreseeable future, the best means
we have available of pursuing and eventually attaining the dual objectives of
rational management of drug resources and
better health for all.

– WORLD HEALTH ORGANIZATION
April 1992

IOCU
International Organization of Consumers Unions